

SUPREME COURT OF THE UNITED STATES

OCTOBER TERM, 1942

No. 717

THE UNITED STATES OF AMERICA, PETITIONER

vs.

JOSEPH H. DOTTERWEICH

ON WRIT OF CERTIORARI TO THE UNITED STATES CIRCUIT
COURT OF APPEALS FOR THE SECOND CIRCUIT

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1 **In the United States Circuit Court of Appeals
For the Second Circuit****UNITED STATES OF AMERICA, COMPLAINANT-APPELLEE**

vs.

**BUFFALO PHARMACAL COMPANY, INC., A CORPORATION, DEFENDANT,
AND JOSEPH H. DOTTERWEICH, DEFENDANT-APPELLANT***Statement under Rule Thirteen*

This proceeding was instituted by the filing of two informations containing a number of counts in the United States District Court for the Western District of New York charging the defendants with a violation of the Federal Food, Drug and Cosmetic Act.

By motion and consent the informations were consolidated and some of the counts dismissed leaving for determination three counts to wit, misbranding of cascara tablets in that these tablets were contained in a bottle which stated, among other things, that they were "Hinkle's Tablets," whereas the national formulary did not permit strychnine sulphate to be included in a "Hinkle" tablet, and, secondly, introducing in interstate commerce digitalis tablets purporting to be one and one-half grains, whereas in fact they contained but half that potency or strength and that this same digitalis was by reason of the potency aforesaid, misbranded, all of which acts it was claimed were in violation of the said Federal Food, Drug and Cosmetic Act (52 Statutes at Large 1040; 21 U. S. C. 331 (a), 351 (b)).

2 After the informations were filed the defendants were arraigned and plead not guilty. A trial with a jury was had in the City of Rochester, New York, beginning June 30, 1941, and ending July 2, 1941.

The trial judge was the Hon. Harold P. Burke, United States Judge in and for the Western District of New York.

At the close of the government's evidence a motion was made in behalf of the defendants for a dismissal of the informations and for a directed verdict of acquittal, which motions were denied and an exception reserved. The same motion was made at the conclusion of the whole case, as well as a motion to set aside the verdict, all of which motions were denied and an exception reserved. The defendant individual, Joseph H. Dotterweich, was convicted of all three counts as charged in the informations, and the jury disagreed as to the defendant corporation, Buffalo Pharmacal Company, Inc.

The sentence of the court was pronounced on October 27, 1941, as follows:

\$500.00 fine on count No. 1.

\$500.00 fine on count No. 2.

\$500.00 fine on count No. 3.

Probations 60 days on each count to run concurrently. Payment of fine suspended on counts 2 and 3.

Hon. George L. Grobe, United States Attorney for the Western District of New York, (Joseph J. Doran, Assistant United States Attorney, of counsel) appeared on the trial for the government. Robert J. Whissel appeared upon the trial for the defendants (Samuel M. Fleischman of Buffalo, of counsel). The same counsel now appears on this appeal. There has been no change of counsel except that on the argument of this appeal, Robert Hitchcock, Assistant United States Attorney, will probably appear for the government in view of the fact that Joseph J. Doran who tried the case has resigned his office.

In the District Court of the United States Within and for the Western District of New York

Information No. 2104C.

UNITED STATES OF AMERICA

v.

BUFFALO PHARMACAL COMPANY, INC., A CORPORATION, AND
JOSEPH H. DOTTERWEICH

Information

George L. Grobe, Attorney for the United States in and for the Western District of New York, who for the said United States Attorney in this behalf prosecutes, in his own proper person comes into court on this 29th day of April, A. D. nineteen hundred and forty, and with leave of court first had and obtained, gives the court here to understand and be informed as follows, to wit:

4

COUNT II

That Buffalo Pharmacal Company, Inc., a corporation organized and existing under the laws of the State of New York, and having its principal place of business in Buffalo, State of New York, and Joseph H. Dotterweich, at the date hereinafter mentioned Secretary and General Manager of said Buffalo Pharmacal

Company, Inc., did, within the Western Judicial District of New York, and within the jurisdiction of this court, on or about the 2nd day of October, in the year nineteen hundred and thirty-nine, then and there, in violation of the Act of Congress of June 25, 1938, known as the Federal Food, Drug, and Cosmetic Act (52 Statutes at Large, 1040; 21 U. S. C., 331 (a), 351 (b)) unlawfully introduce and deliver for introduction in interstate commerce, to wit, ship, via United States Parcel Post, from Buffalo, State of New York, to Homer City, State of Pennsylvania, consigned to Dr. M. M. Palmer, a certain consignment, to wit, one bottle, containing an article designed and intended to be used as a drug, which said bottle was, then and there, denominated as to the contents thereof, and labelled, marked, and branded as follows, to wit:

No. 200
1000 TABLETS
CASCARA
COMPOUND
No. 2
S. C. Pink
(Hinkle)

Cascarin	1/4 gr.
Aloin	1/4 gr.
Podophyllia	1/6 gr.
Ext. Belladonna	1/6 gr.
Strychnine Sulphate	1/60 gr.
Oleo. Ginger	1/16 gr.

6751

Manufacture from high quality
materials for
BUFFALO
PHARMACAL CO.
Buffalo, N. Y.

That said article of drugs, when introduced and delivered for introduction in interstate commerce as aforesaid, was then and there adulterated within the meaning of said Act of Congress, in that said article purported to be and was represented as a drug which is recognized in an official compendium, to wit, the National Formulary, under the names "Compound Pills of Cascara" and "Hinkle's Pills," and its strength differed from and its quality and purity fell below the standard set forth in said compendium official at the time of investigation of the said article, in that the said article contained strychnine sulphate, whereas the formula set forth in the said National Formulary, official at the time of investigation of the article, as the standard for

compound pills of cascara (Hinkle's pills), does not include strychnine sulphate; and the difference in strength, quality, and purity of the said article from the standard set forth in said compendium was not stated plainly on the label; contrary to the form of the statute in such case made and provided and against the peace and dignity of the United States of America.

COUNT III

6 And the said United States Attorney, in manner and form as aforesaid, also gives the court here to understand and be informed that Buffalo Pharmacal Company, Inc., a corporation organized and existing under the laws of the State of New York, and having its principal place of business in Buffalo, State of New York, and Joseph H. Dotterweich, at the date hereinafter mentioned Secretary and General Manager of said Buffalo Pharmacal Company, Inc., did, within the Western Judicial District of New York, and within the jurisdiction of this court, on or about the 2nd day of October, in the year nineteen hundred and thirty-nine, then and there, in violation of the Act of Congress of June 25, 1938, known as the Federal Food, Drug, and Cosmetic Act (52 Statutes at Large, 1040; 21 U. S. C., 331 (a), 352 (a)) unlawfully introduce and deliver for introduction in interstate commerce, to wit, ship, via United States Parcel Post, from Buffalo, State of New York, to Homer City, State of Pennsylvania, consigned to Dr. M. M. Palmer, a certain consignment, to wit, one bottle, containing an article designed and intended to be used as a drug, which said bottle was, then and there, denominated as to the contents thereof, and labeled, marked, and branded as more fully described in the third count of this information, and which said description in said third count is, by reference, hereby incorporated in this count.

That said article of drugs, when introduced and delivered for introduction in interstate commerce as aforesaid, was then and there misbranded within the meaning of said Act of Congress in that the statement, to wit, "Tablets Cascara Compound" * * * (Hinkle), borne on the label attached to the bottle containing the article, regarding the article, was false and misleading, in this, that the said statement purported and represented that said

7 article consisted of tablets of compound cascara (Hinkle), a drug recognized in the National Formulary under the names "Compound Pills of Cascara" and "Hinkle's Pills," whereas, in truth and in fact, said article did not consist of tablets of compound cascara (Hinkle), in that said article contained strychnine sulphate, an ingredient which is not included in the formula set forth as the standard for compound pills of

cascara (Hinkle's pills) in the National Formulary, official at the time of investigation of the article; contrary to the form of the statute in such case made and provided and against the peace and dignity of the United States of America.

GEORGE L. GROBE,
United States Attorney,
For the Western District of New York.

(Verified by George L. Grobe, April 26, 1940.)

In the District Court of the United States Within and for the
Western District of New York

Information No. 2190C—August Term, 1940.

UNITED STATES OF AMERICA.

v.

BUFFALO PHARMACAL COMPANY, INC., A CORPORATION, AND
JOSEPH H. DOTTERWEICH

Information

George L. Grobe, Attorney for the United States in and
for the Western District of New York, who for the said
United States Attorney in this behalf, prosecutes, in his
own proper person comes into court on this 5th day of August
A. D., nineteen hundred and forty, and with leave of court first
had and obtained, gives the court here to understand and be
informed as follows, to wit:

COUNT 3

That Buffalo Pharmacal Company, Inc., a corporation organized and existing under the laws of the State of New York, and having its principal place of business in Buffalo, State of New York, and Joseph H. Dotterweich, at the date hereinafter mentioned President and Secretary of said Buffalo Pharmacal Company, Inc., did, within the Western Judicial District of New York, and within the jurisdiction of this court, on or about the 8th day of January in the year nineteen hundred and forty, then and there, in violation of the Act of Congress of June 25, 1938, known as the Federal Food, Drug and Cosmetic Act (52 Statutes at Large, 1040; 21 U. S. C., 331 (a), 331 (c)), unlawfully introduce and deliver for introduction in interstate commerce, to wit, ship, via United States Parcel Post, from Buffalo, State of New York, to Rock Creek, State of Ohio, consigned to H. O. Tagett, M. D.,

a certain consignment, to wit, one bottle, containing an article designed and intended to be used as an article of drugs, which said bottle was, then and there, denominated as to the contents thereof, and labeled, marked and branded as follows, to wit:

9.

No. 267
1060
TABLETS
DIGITALIS
 $1\frac{1}{2}$ GRS.
CT
ONE USP UNIT
Represents
(0.1 gram)
equals
1.543 grains)
Powdered Digitalis
Manufactured from HIGH QUALITY
materials for
BUFFALO
PHARMACAL CO.
Buffalo, N. Y.

That said article of drugs, when introduced and delivered for introduction in interstate commerce, as aforesaid, was then and there adulterated within the meaning of said Act of Congress, in that its strength differed from and its purity or quality fell below that which it purported and was represented to possess, in that each tablet of said article was represented to possess a potency of one U. S. P. digitalis unit, whereas, in truth and in fact, each tablet of said article possessed a potency of less than one U. S. P. digitalis unit, to wit, not more than 0.48 U. S. P. digitalis unit per tablet; contrary to the form of the statute in such case made and provided and against the peace and dignity of the United States of America.

COUNT 4

And the said United States Attorney, in manner and form as aforesaid, also gives the court here to understand and be informed that Buffalo Pharmacal Company, Inc., a corporation organized and existing under the laws of the State of New York, and having its principal place of business in Buffalo, State of New York, and Joseph H. Dotterweich, at the date hereinafter mentioned, President and Secretary of said Buffalo Pharmacal Company, Inc., did, within the Western Judicial District of New York, and within the jurisdiction of this court, on or

about the 8th day of January, in the year nineteen hundred and forty, then and there, in violation of the Act of Congress of June 25, 1938, known as the Federal Food, Drug, and Cosmetic Act (52 Statutes at Large, 1040; 21 U. S. C., 331 (a) 352 (a),) unlawfully introduce and deliver for introduction in interstate commerce, to wit, ship, via United States Parcel Post, from Buffalo, State of New York, to Rock Creek, State of Ohio, consigned to H. O. Tagett, M. D., a certain consignment to wit, one bottle, containing an article designed and intended to be used as a drug, which said bottle was, then and there, denominated as to the contents thereof, and labeled, marked and branded as more fully described in the first count of this information, and which said description in said first count is, by reference, hereby incorporated in this count.

That said article of drugs, when introduced and delivered for introduction in interstate commerce, as aforesaid, was then and there misbranded within the meaning of said Act of Congress, in that the statement, to wit, "Tablets Digitalis 1½ Grs. * * * One USP Unit Represents (0.1 gram equals 1.543 grains) Powdered Digitalis," borne on the label attached to the bottle containing the article, regarding the article, were false and misleading, in this, that the said statements represented that each tablet of said article possessed a potency of less than one U. S. P. digitalis unit, to wit, not more than 0.48 U. S. P. digitalis unit per tablet; contrary to the form of the statute in such case made and provided and against the peace and dignity of the United States of America.

GEORGE L. GROBE,
United States Attorney,
For the Western District of New York.

(Verified by George L. Grobe, August 1, 1940.)

In United States District Court

No. 2190-C

[Title omitted.]

*Stipulation as to Interstate Shipment of Digitalis Tablets
(Government's Exhibit No. 13 in Evidence)*

It is hereby stipulated by and between the attorneys for all of the parties to the above entitled proceeding that the following facts are stipulated to and agreed upon, namely, that within the Western District of New York, on or about January 8, 1940, there was introduced and delivered for introduction in interstate com-

merce and shipped via United States Parcel Post from Buffalo, New York to Rock Creek, in the State of Ohio, consigned 12 to H. O. Tagett, M. D., a certain consignment, to wit, one bottle, containing an article designed and intended to be used as an article of drugs, which said bottle was then and there denominated as to the contents thereof and labeled, marked and branded as follows, to wit:

No. 267
1000
TABLETS
DIGITALIS
1½ GRS.
C T
ONE USP UNIT
Represents
(0.1 gram
equals
1.543 grains)
Powdered Digitalis
Manufactured from HIGH QUALITY
materials for
BUFFALO
PHARMACAL CO.
Buffalo, N. Y.

That on or about February 29, 1940, at Rock Creek, Ohio, one John S. Faries, Inspector, Food & Drug Administration, Federal Security Agency, purchased from H. O. Tagett, M. D., a portion of the shipment and consignment hereinabove mentioned and described, which said purchase was taken from the original bottle labeled as aforesaid, and that immediately after said purchase said John S. Faries left same in the original bottle, properly sealed, and marked the same "78786-D, 2-29-40, John S. Faries," and transmitted said bottle and its contents, so sealed and 13 marked, and in the same condition as when purchased, to the Food & Drug Administration, Washington, D. C., via Parcel Post. That from said identical consignment, shipped, purchased and transmitted, as aforesaid, and upon the request of the defendants, there was delivered to the defendants, or on or about March 21, 1941, a portion of said sample.

It is further stipulated that the facts hereinabove stated, stipulated to and agreed upon are admitted by the parties to the above-entitled proceeding for the purpose of the trial of the above numbered information, and that at said trial thereof

neither the United States of America nor the defendants need call witnesses in order to establish said facts, and that this stipulation may be received in evidence and considered by the Court and Jury as proof of the facts hereinabove agreed upon in lieu of any of the parties hereto calling witnesses for the purpose of establishing said facts.

Dated, Buffalo, N. Y., June —, 1941.

United States Attorney for the Western District of New York, Attorney for United States of America.

Attorney for Buffalo Pharmaceutical Company, Inc., and Joseph H. Dotterweich, defendants above named.

Attorney for Buffalo Pharmaceutical Company, Inc., and Joseph H. Dotterweich, defendants above named.

14 In United States District Court
No. 2104-C

[Title omitted.]

*Stipulation as to Interstate Shipment of Cascara.
(Government's Exhibit No. 14 in Evidence)*

It is hereby stipulated by and between the attorneys for all of the parties to the above-entitled proceeding that the following facts are stipulated to and agreed upon by and between the parties, namely, that on or about August 16, 1939, at and within the Western District of New York, there was introduced and delivered for introduction in interstate commerce, to wit, from Buffalo, New York, to Erie, Pennsylvania, via United States Parcel Post, consigned to Dr. G. E. Becker, a certain consignment, to wit, 2 cartons, each carton containing 6 ampoules, each ampoule containing an article designed and intended to be used as a drug, which said cartons and ampoules were then and there denominated as to the contents thereof, and labeled, marked and branded as follows, to wit:

(Carton) : No. 1781 6 Ampoules. $\frac{1}{2}$ cc Size
POSTERIOR PITUITARY SOLUTION USP STRENGTH
For Obstetrical Use.
Physiologically Standardized.
Not more than 0.5% chlorbutanol (chloroform deriv.) is present
as a preservative.

15 Each ampoule contains a sufficient amount to permit withdrawal and administration of $\frac{1}{2}$ cc.

Dose: $\frac{1}{4}$ to 1 cc subcutaneously or intramuscularly.

Not recommended for use after Jan 6 '41

6826

BUFFALO PHARMACAL CO., Inc.

BUFFALO, N. Y.

(Ampoule label):

$\frac{1}{2}$ cc Size

Pituitary Solution

USP Strength

For Obstetrical Use

Chlorb. (chlo. der.) .5%

Buffalo Pharmacal

Company, Inc.

by Buffalo Pharmacal Company, Inc., a domestic corporation, having its principal place of business in the City of Buffalo, New York. Further, that on or about August 23, 1939, at Erie, Pennsylvania, John S. Faries, Inspector of the Food and Drug Administration, Federal Security Agency, purchased from G. E. Becker, M. D., a sample of Ampoules Posterior Pituitary Solution USP, consisting of 2 boxes, 6 ampoules each, and which said sample so purchased was the identical same consignment hereinbefore mentioned in this paragraph and shipped by Buffalo Pharmacal Company, Inc., in interstate commerce from Buffalo, New York, to Erie, Pennsylvania, on or about August 16, 1939, as hereinabove stated. Further, that immediately after purchasing said sample, the said John S. Faries properly sealed and

designated the same as "78710-D 8-23-39, John S. Faries,"

16 and transmitted said sample, so sealed and marked and in the identical condition as when purchased by him, to the Food & Drug Administration, Federal Security Agency, Washington, D. C. That from the said consignment so shipped and purchased as aforesaid, and sealed, identified and delivered to the Food & Drug Administration at Washington, D. C., there was delivered to the defendants above named a portion thereof upon their request therefor. That said consignment hereinbefore mentioned was shipped in interstate commerce by the means aforesaid from Buffalo, New York, to Erie, Pennsylvania, on or about August 16, 1939, by Buffalo Pharmacal Company, Inc., a corporation and a defendant named in the above proceeding.

It is further stipulated that on or about October 2, 1939, within the Western Judicial District of New York, there was introduced and delivered for introduction in interstate commerce, and

shipped, via United States Parcel Post, from Buffalo, New York, to Homer City, in the State of Pennsylvania, consigned to Dr. M. M. Palmer, a certain consignment, to wit, one bottle; containing an article designed and intended to be used as a drug, which said bottle was then and there denominated as to the contents thereof, and labeled, marked and branded as follows, to wit:

No. 200
 1000 TABLETS
 CASCARA
 COMPOUND
 No. 2
 S. C. Pink
 (HINKLE)

Cascarin	1/4 gr.
Aloin	1/4 gr.
Podophyllin	1/8 gr.
Ext. Belladonna	1/8 gr.
Strychnine Sulphate	1/160 gr.
Oleo. Ginger	1/16 gr.

17

6751

Manufactured from high quality
 materials for
 BUFFALO
 PHARMACAL CO.
 Buffalo, N. Y.

That said consignment of said articles of drugs was introduced and delivered for introduction and shipped in interstate commerce, as aforesaid, on or about said date, by Buffalo Pharmacal Company, Inc., a corporation then having its principal place of business in the City of Buffalo, New York and a defendant named in the above styled proceeding. That on or about October, 24, 1939, at Homer City, Pennsylvania, one John S. Faries, Inspector of the Food & Drug Administration, Federal Security Agency of the United States, purchased from M. M. Palmer, M. D., the consignment and shipment mentioned and described and shipped as stated in the preceding sentence, which said sample so purchased was labeled as described and set forth in the preceding sentence. That immediately upon purchasing the aforesaid shipment and sample the said John S. Faries, sealed the same, designated and marked the same as "78814-D, 10-24-39, John S. Faries," and transmitted the said sample, so sealed and marked and in the identical condition as when purchased by him, to the Food & Drug Administration, Buffalo, New York. That the purchase so made by said John S. Faries, identified, 18 designated and transmitted, was the identical shipment in-

roduced in and shipped in interstate commerce from Buffalo, New York to Homer City, Pennsylvania on or about October 2, 1939 by the defendant, Buffalo Pharmacal Company, Inc., as aforesated.

It is further stipulated that neither the United States of America nor the defendants need call witnesses to establish the facts agreed upon in the foregoing paragraphs, and that the facts contained herein, stipulated to and agreed upon, may be submitted to the Court and jury on the trial of the above information, as so agreed upon in lieu of the testimony of witnesses in support thereof, and this stipulation received in evidence and considered by the Court and jury as proof of the facts herein contained.

Dated, Buffalo, N. Y., June —, 1941.

*United States Attorney for the
Western District of New York,
Attorney for United States of America.*

*Attorney for Buffalo Pharmacal Company, Inc.,
and Joseph H. Dotterweich, defendants above named.*

*Attorney for Buffalo Pharmacal Company, Inc.,
and Joseph H. Dotterweich, defendants above named.*

19

In United States District Court

[Title omitted.]

Clerk's Minutes

Copy of Minutes of U. S. District Court re above cases: April 29, 1940.

Leave first having been obtained and granted, Asst. U. S. Attorney Hitchcock filed informations as follows:

U. S. v. Buffalo Pharmacal Company, Inc., a corporation =
Joseph H. Dotterweich #

Aug. 5, 1940.

On motion of Asst. U. S. Atty. Doran leave is granted to file the following information:

U. S. vs. Buffalo Pharmacal Company, Inc., a corporation, and
Joseph H. Dotterweich Cr. C.

20 March 11, 1941

Defts, being duly arraigned enter pleas of not guilty as follows:

Cr. 2190-C U. S. v. Buffalo Pharmacal Co. Inc., plea by attorney Robert J. Whissel.

Cr. 2104-C U. S. v. Joseph H. Totterweich.

March 31, 1941

Cr. 2104-C.

Cr. 2190-C Buffalo Pharmacal Co. Inc. & Joseph H. Dotterweich.

Motions to quash informations.

Joseph J. Doran, Asst. U. S. Atty. appears for Govt.

Robert J. Whissel, Esq., appears for defts.

Briefs to be finally submitted 4/7/41.

May 20, 1941

Cr. 2104-C U. S. v. Buffalo Pharmacal Company, Inc. and Cr. 2190-C Joseph H. Dotterweich.

Order denying motion to quash.

June 30, 1941.

Cr. 2104-C U. S. vs. Buffalo Pharmacal Company, Inc., a corporation and Joseph H. Dotterweich.

Cr. 2190-C U. S. vs. Buffalo Pharmacal Company, Inc., a corporation and Joseph H. Dotterweich.

Cases are reached for trial.

Appearances:

Joseph J. Doran, Asst. U. S. Atty., for Govt.

Samuel Fleishman, Esq., for defts.

Robert Whissel, Esq., for defts.

Mr. Doran moves to consolidate informations 2104-C and 2190-C.

Motion granted. Order consolidating informations 2104-C and 2190-C.

21 Exception by defendants.

Mr. Doran moves the case for trial.

Mr. Doran moves to dismiss counts 1, 2, 3 of information No. 2104-C.

The motion to dismiss counts 1, 2, 3, of information No. 2104-C is granted.

The following jury is duly empanelled, and the case proceeds to trial.

1. Carrie S. Lovett	7. Foster F. Spencer
2. M. Josephine Brown	8. Bertha A. Bush
3. Clara E. Britton	9. Dorothy L. Duan
4. Florence C. Anderson	10. Gordon L. Fox
5. Joseph M. Marthage	11. Maude M. Eberle
6. Margaret J. Anderson	12. Catherine Dick

The Court orders 2 alternate jurors empanelled as follows:

1. Harry C. Dennis

2. John H. Barringer

Mr. Doran opens for Govt.

Mr. Fleishman opens for defts.

Witnesses for Govt.:

Irene Steinhauser, John S. Faries, Arthur William Mumm, Clarence W. Graser, Solomon M. Berman, Herbert A. Braun.
Trial adjourned until tomorrow at 10 A. M.

July 1, 1941

Cr. 2104-C) U. S. v. Buffalo Pharmacal Company, Inc. & 1

2190-C) Trial continued from yesterday with the Consolidated) same appearance and jury.

22 Witnesses for Govt.:

Harold O. Taggett, Herbert A. Braun (recalled) Lloyd C. Miller, Clifford W. Chipman, Elwood H. Snider, Theodore F. Pappe.

Government rests.

Mr. Fleishman moves to dismiss the information against Deft. Dotterweich, etc.

Decision reserved.

July 2, 1941

Cr. 2104-C) U. S. vs. Buffalo Pharmacal Company, Inc. & 1

2190-C) Trial continued from yesterday with the Consolidated) same appearances and jury.

Motions by Mr. Fleischman to dismiss informations are denied.

Witnesses for Defts.

Lloyd C. Miller (re-called), Maurice Gracer (stenographer) Joseph H. Dotterweich, Arthur J. Meier, Joseph H. Dotterweich (recalled), Arthur J. Jeier (recalled).

Defts. rest.

Witnesses for Govt. in rebuttal.

George L. Keenan.

Witnesses for defts.

Arthur J. Meier (recalled), Lloyd C. Miller (recalled).

Arthur J. Meier (recalled).

Witnesses for Govt.

Joseph H. Dotterweich (recalled).

Both sides rest.

23 Mr. Fleishman renews his motions to dismiss the informations and moves for a direction of a verdict in favor of defts. etc. Motions denied.

Mr. Fleishman sums for defts.

Mr. Doran sums for Govt.

After listening to a charge by his honor the Judge, the Jury retire at 4:00 P. M., in the custody of sworn officers to deliberate upon their verdict. (Alternative jurors discharged).

The Jury is ordered taken to supper at the expense of the Govt.
The Jury return at 11:02 P. M. with a verdict finding the
deft. Joseph H. Dotterweich guilty as charged in the information
and report that they cannot agree upon a verdict as to the deft.
Buffalo Pharmacal Co. whereupon they are discharged by the
Court.

All motions reserved.

Sentence deferred.

Sept. 8, 1941

Cr. 2104-C) U. S. v. Joseph H. Dotterweich.

Cr. 2190-C) Hearing on argument by counsel.
Consolidated)

Appearances:

Samuel Fleishman, Esq., for Deft.

Robert Whissel, Esq., for Deft.

Joseph J. Doran, Asst. U. S. Atty. for Govt.

Memo submitted.

Held—Sentence deferred.

Oct. 27, 1941

Cr. 2104-C) U. S. vs. Joseph H. Dotterweich Deft. appears

Cr. 2190-C) for sentence, whereupon the Court on motion of
Asst. U. S. Atty. Doran sentences deft. as follows:

24 \$500.00 fine on count 1;
 \$500.00 fine on count 2.

\$500.00 fine on count 3,

Payment of fine suspended on counts 2 and 3 (with counsel).

Probation 60 days on each count to run concurrently.

Order denying motion to set aside verdict.

In United States District Court

[Title omitted.]

**Bill of exceptions*

Trial before Hon. Harold P. Burke, District Court Judge, and
a jury, at the Court Room, Federal Building, Rochester, N. Y.,
beginning June 30, 1941, 10:30 A. M.

Appearances:

George L. Grobe, Esq., U. S. District Attorney, by Joseph J.
Doran, Esq., Assistant U. S. District Attorney, appearing for the
Government.

Samuel M. Fleischman, Esq., appearing for defendants. Rob-
ert J. Whissel, Esq., Counsel.

25 IRENE STEINHAUSER, called as a witness on behalf of the Government and sworn, testified as follows:

Direct examination by Mr. DORAN:

Q. Your name is Irene Steinhauser?—A. Right.

Q. Will you try to speak up so the jurors over here can hear you?—A. Yes.

Q. Where do you live?—A. 80 Phyllis Avenue, Buffalo.

Q. Was there a time when you were employed by the Buffalo Pharmacal Company, Inc.?—A. Yes.

Q. And that was a corporation, is that right?—A. Yes.

Q. For how long were you employed by that company, Miss Steinhauser?—A. I would say about five months.

Q. Do you recall a period of time, approximately, that you were employed there?—A. I started there sometime in July, I don't know the exact date.

Q. What year?—A. July 1940.

Q. And you were there for how long?—A. Until January, January 1941, right after the first of the year.

Q. In what capacity were you employed by that corporation?—A. Well, I worked in the bottling department.

Q. The what?—A. The bottling department.

Q. Where is the place of business in Buffalo, the Buffalo Pharmacal Company, Inc.?—A. On Oak Street.

Q. On Oak Street, in Buffalo?—A. That is right.

Q. And about how many employees did it have, the company, when you were there, if you know?—A. I would say about 26: somewhere around there.

Q. About 26 employees?—A. Yes.

Q. All of these people, did they, did all of these 26 employees work at the one place of business?—A. Yes; they all worked in the one plant.

26 Q. And just tell us briefly what sort of a plant it was, that is, the physical make-up of the place of business?—A. Well, it was on the upper floor and the offices were in the front, and then directly behind the offices was the printing department and behind that was the bottling department, and in back was the lab for the chemists, and on the other side was the shipping room.

Q. Now, all of these departments of the company, were they on the same floor?—A. They were on one floor.

Q. Were they partitioned off, or all in one, altogether?—A. They were partitioned off.

Q. Do you know Joseph Dotterweich, the defendant in this proceeding?—A. Yes.

Q. You have known him for how long, Miss Steinhauser?—A. Well, since—well, I met him before I went to work there.

Q. You knew him before you went to work there?—A. Yes.

Q. Was he connected with the Buffalo Pharmacal Company, Inc., during the period that you were employed there?—A. I want to object to that, that is, too broad a question connected with it; as to employees.

Mr. DORAN. I will bring out the details of it; I simply want an affirmative or a negative answer.

Q. Was he connected with the company then?—A. Yes.

Q. In what way?—A. I always understood—

Mr. FLEISCHMAN. I object to what she understood.

The COURT. She was an employee and I think an employee is in a better position to judge that.

Mr. FLEISCHMAN. That calls for a conclusion.

The COURT. You tell what you regarded him as, describe what his duties were.

27 The WITNESS. Well, he was the boss of the company.

Q. He was the boss?—A. Yes.

Mr. FLEISCHMAN. I move to strike it out.

The COURT. That is rather a loose term. Strike it out.

Q. What were his duties as you observed?—A. He was in charge; he was over everyone else.

Q. When you speak of everyone else, you mean the employees, is that it?—A. Yes.

Q. How much time did he spend there at the place of business, Miss Steinhauser?—A. He was there most every day all day.

Q. Would you say that he spent full time there during business hours of the day as far as you know when you were there?—A. Yes.

Q. And do you know whether he had a title at that time of any kind?—A. No, I don't.

Q. Was he known as the general manager, for example, do you know?—A. No; I never heard him spoken of in that way.

Q. Or president, or anything like that?—A. No; I never heard him spoken of in that way.

Q. You say there were about 28 employees there at the time?—A. About that many, I wouldn't say, but approximately that.

Q. What is the business generally of that corporation?—A. Well, they bottled tablets mostly, and some solutions; bottles and packages and shipped them out.

Q. Was there any manufacturing done there?—A. Not that I know of; most of it was brought in.

Q. The drugs had already been manufactured, is that it
28 and brought in there for bottling and shipping; is that right?—A. Yes.

Q. And these tablets were what; the medicines and drugs of different kinds?—A. They were tablets; they were drugs brought in there in bottles and in packages.

Q. Was there any person there, while you were employed there, as far as you know that had anything to do, so far as supervising or directing the employees of the corporation other than Mr. Dotterweich?—A. No; only at times when he was away, Arthur Munn would be in charge.

Q. While Mr. Dotterweich was away?—A. Yes.

Q. You mean by that, when Mr. Dotterweich was present, always in charge?—A. Yes.

Q. Do you know how many employees that had to do with shipping, Miss Steinhauser?—A. Well, I know that two of them packaged it, and the one that was in charge of the shipping.

Q. Who were the two that packaged it, can you give their names?—A. One was Richard Statone.

Q. Who was the other one?—A. And the other one was George—no, I don't remember his name, I was never in that part much.

Q. George someone, you don't know the last name, is that it?—A. Yes.

Q. So that as far as you observed, there were only two of the employees that were directly engaged in the shipping end of the business, is that right?—A. That is right.

Q. Who was in charge of the shipping?—A. Arthur Munn was in charge of the shipping room.

Mr. DORAN. You may ask.

Cross-examination by Mr. FLEISCHMAN:

Q. Just a few questions. Did you ever see any pills in that place?—A. Yes.

29 Q. Pills or tablets, both, or either?—A. What is the difference?

Q. Do you—do you know what a pill is?—A. Yes.

Q. Do you know what a tablet is?—A. Yes.

Q. You know the difference then?—A. Well, no—

Q. Did you ever see the little round pills sold in your place, any of these pills?—A. Yes.

Q. What is digitalis?—A. Well, I remembered working on digitalis.

Q. Is it pills or did you see any cascara pills—Hinkel pills—did you ever see those there?—A. I don't remember.

Q. Did you ever see anyone in your establishment mix up anything other than what you got to bring about, a different result from what you saw from the outside?—A. No, I didn't.

Q. Then as I get it, what you try to tell the District Attorney is you would get stuff from the large wholesale houses?—A. Yes.

Q. The Norwich Manufacturing Company, for instance?—A. Yes.

Q. Lilly & Company?—A. I don't remember that name.

Q. Do you recall the names of Arner & Company and Pennock & Company?—A. I don't remember those.

Q. They would ship stuff to you?—A. Yes.

Q. Then all you did, you would take what was shipped in by the other concerns, repack it and ship to your customers?—A. Yes.

Q. But there was no compounding of any drugs by your people at all?—A. No.

Q. And your work was in the bottling department?—A. Yes.

Q. Do you know that the instructions you had, those things had to be packed in air-tight containers, and you put them in such?—A. Yes.

Q. And you did your work there?—A. Yes.

Q. That is what you did during the time you were there?—A. Yes.

Q. For instance, digitalis has to be packed in airtight containers?—A. Yes.

Q. When digitalis would come from Arner & Company, there was a lot came from them?—A. Yes.

Q. And they had to be sent out to doctors and they were packed from the original package of Arner & Company into the packages that you had there, the air-tight packages, and when they were in proper shape to be shipped out, no doubt it went out to the doctors; is that correct?—A. Yes.

Mr. FLEISCHMAN. That is all, thank you.

JOHN S. FARIES, called as a witness on behalf of the Government, and sworn, testified as follows:

Direct Examination by Mr. DORAN:

Q. Mr. Faries, where do you live?—A. In Pittsburgh, Pennsylvania, at the present.

Q. What is your occupation?—A. I am an inspector for the Food & Drug Administration.

Q. And that is an agency of our Government?—A. It is an agency of our Government, one of the Federal Security Agencies.

Q. How long connected with the Food & Drug Administration?—A. Since 1930.

Q. Approximately 11 years?—A. Yes.

Q. Have you been an inspector all during that period?—A. Yes.

31 Q. Briefly what are your duties, Inspector?—A. The duties of an inspector are extremely diversified. Primarily they fall into two groups, inquiries into the factory supply in the field of the products shipped. There is the food policy and the drugs, which present general inspection, warehouse inspection, the actual inspection of the Food & Drug Administration, and coming under the food and the cosmetics.

Q. You speak of the field inspection. Tell us about that.—A. In the field we collect samples of products shipped in interstate commerce for examination, and the laboratory is sometimes directed to determine whether they comply with the Food, Drug and Cosmetic Act. We collect the samples, we identify the sale and transmit it to the laboratory. The laboratory does the great bulk of the examinations. In this case, they did both of the examinations.

Q. That is, those tests are made for strength, purity, and quality?—A. And the compliance with all the requirements of the law, either in the labeling or the composition.

Mr. DORAN. Will you mark this for identification? (Bottle of cascara tablets marked "Government's Exhibit Number 1" for identification.)

Q. I show you Government's Exhibit Number 1 for identification, Mr. Faries, and ask you if you will please examine it and after you have examined it, I will ask you to state whether or not you have seen it before.—A. Yes, my original seal, or a portion of it rather, it has been opened since I sealed it. It still shows—

Q. Just tell whether you saw it before.—A. Yes.
Q. When did you first see it?—A. When I collected the sample on October 24, 1939.

32 Q. Where was that?—A. That was in Homer City, Pennsylvania.

Mr. FLEISCHMAN. The date, please.

Mr. DORAN. 10-24-39.

The WITNESS. Yes.

Q. Where in Homer City, Pennsylvania, did you first see it?—A. At the office of a practicing physician, Dr. M. M. Palmer.

Q. How did you happen to see that?—A. Well, in the field, a large aspect of our work is the checking of drug products and we visit a large number of doctors for the primary purpose, almost the sole purpose of collecting these samples for checking the compliance with the Food, Drug & Cosmetic Act, that is in the field. I never saw him before I got this sample.

Q. That is, in one of your routine check-ups, picking up samples from doctors, is that right?—A. Yes.

Q. In what condition was the exhibit when you first saw it?—
A. It was a sealed, or a cellophane wrapped package, with an original label on, which has since been stripped, as it has a little bit on the top of the bottle.

Mr. DORAN. Will you also mark this for identification? (Cascara compound label marked Government's Exhibit No. 2 for identification.)

Q. I show you Exhibit Number 2 for identification and call your attention specifically to that portion of it, which is the label pasted on the white paper, and that which we are interested in only is the yellow paper, and I ask you if you saw that before?—
A. yes, sir; I have. This is the original label, that was originally on this bottle, since the number corresponds with the number on the seal which still remains on the bottle.

33 Q. That is the yellow label on Exhibit Number 2 is on the bottle Exhibit Number 1, or was, when you first saw it?—A. Yes.

Q. You said that the bottle was closed in the cellophane wrapper, is that right?—A. Yes, sir.

Q. What sort of a top was on it?—A. This top here, presumably, that is the appearance of all the tops of the Buffalo Pharmaceutical Company.

Mr. FLEISCHMAN. I cannot hear you.

The WITNESS. It is a plastic screw-cap top on the bottle.

Q. There were tablets in it?—A. Yes.

Q. Was it full?—A. Well, up to approximately the shoulder. I don't just recall that specifically, but it is customary to fill the bottles up to there.

Q. What did you do with Exhibit Number 1, which is labeled with Exhibit Number 2, when you picked it up first?—A. I identified the bottle you see here, identified it.

Mr. FLEISCHMAN. This is all covered by the stipulation and anything offered here is just a waste of time.

Mr. DORAN. I want to get them in evidence. I appreciate your courtesy, but at the same time—

The COURT. Why don't you offer in evidence?

Mr. DORAN. I offer them in evidence.

Mr. FLEISCHMAN. No objection.

The COURT. Received.

(Government's Exhibits Numbers 1 and 2 for identification received in evidence.)

Q. What did you do then with it?—A. I transmitted it in by mail to the Buffalo Station of the Feed & Drug Administration in the Federal Building in Buffalo, after I marked and sealed it.

34 Mr. DORAN. I offer in evidence, bottle containing certain tablets regularly labeled "Digitalis, 1½ grains, C. T. one U. S. P. unit, Buffalo Pharmacal Company."

The COURT. Received.

(Bottle containing tablets labeled as above, marked "Government's Exhibit Number 3" in evidence.)

Q. I show you Government's Exhibit 3 and ask you whether you saw that before and if so, where?—A. Yes, sir.

Q. When?—A. This is the bottle still bearing the original label which I purchased from Dr. H. J. Tagett, Rock Creek, Ohio, on February 29, 1940.

Q. Is that a sample picked up in the course of one of your usual field check-ups that you mentioned?—A. Yes, it is.

Q. And he was the practicing physician, I suppose, who was there at the time?—A. Yes; and is I still believe.

Q. What did you do with the —A. I transmitted this sample after sealing and identifying it, to the Washington office of the Food & Drug Administration, since it involved a different type of assay than the other one.

Q. Tell us the condition of the exhibit when you first saw it.—A. Essentially in the condition it is now, the bottle containing the tablets with a lid on it.

Q. You say a "lid" do you mean one of these plastic caps?—A. Yes; the same type I presume, that is the original cap.

Mr. FLEISCHMAN. I object to what you presume and I move to strike it out.

The COURT. Strike it out.

The WITNESS. It had a cap on it at the time I collected the bottle.

35 Q. A plastic cap?—A. A plastic cap.

Q. Where was it?—A. In the doctor's drug room which adjoined his office.

Q. Was it in the same condition, except for the white seals which are contained thereon?—A. Yes, sir.

Q. This same label, the yellow label that is marked Number 267 on there, the label and red label was on the bottle when you first picked it up?—A. Yes, sir.

Mr. DORAN. You may ask.

Cross-examination by Mr. FLEISCHMAN:

Q. Are you Dr. Faries?—A. No, sir.

Mr. Faries, I take it from your long experience in this work that you know these bottles when you see them, I mean when you pick up the pills and tablets as the case may be, you know what you are looking at. You don't assay anything?—A. No; I am not an analyst.

Q. Now, therefore, in the bottle, it purports to contain digitalis tablets?—A. Yes.

Q. I want to come back to your answer that it has some kind of a top on it.—A. A screw cap.

Q. Is that the usual way in which they are packed?—A. Yes, sir.

Q. That is to say, on the outfits that you have seen that is the way they are capped and that meets with the Government form of cap?—A. That is the custom.

Q. Well, it is the same type?—A. Yes.

Q. And that keeps the contents in fair shape with that cap on there?—A. I assume so.

Q. Would you like to cap it differently if you had your way?—A. No, sir.

Q. Now, this bottle was on the shelf of the Doctor's drug room and you bought it?—A. Yes.

36 Q. Why did you buy it?—A. Because it is our custom to obtain samples, important to furnish them, to determine if the various firms keep their products up to standard.

Q. After you purchased this bottle, which is Government's Exhibit Number 4, the digitalis, did you turn it over to the Government?—A. I shipped it to the Washington office.

Q. Well now, you knew, did you not, where this had come from, this exhibit?—A. Oh, yes.

Q. Where?—A. From the Buffalo Pharmaceutical Company, for two reasons.

Q. Well, did you know where Dr. Tagett got this bottle from?—A. Yes.

Q. And then this bottle, upon it was contained the name of the Buffalo Pharmaceutical Company, their label?—A. Yes, sir.

Q. And when you wanted to make an investigation of the Buffalo Pharmaceutical Company, they told you that bottle was in exactly the same condition, the way they shipped it to Dr. Tagett, from the Pharmaceutical Company?—A. I had no such experience with this product.

Q. When you bought it, that was the end of your work?—A. I transmitted it to the Washington office; yes.

Q. Now, do you know that Arner & Company are large manufacturers of pills and tablets and drugs, a very large concern?—A. Yes.

MR. DORAN. That is objectionable, no charge against them or their standing, not an issue here. It is immaterial, I submit.

MR. FLEISCHMAN. I think it is very important and what we are eventually coming to, as to its strength when it left Arner & Company.

37 **Mr. DORAN.** I might say right here, that I think that if we can come to an understanding with your Honor as to whether that question of good faith, we are going to save a lot of time. We do not contend that there was any direct adulteration by this concern or any other concern. We intend to prove that it moved in interstate commerce, so that the question of good faith or the precautions that this company or the Arner & Company may or may not have taken, that is not in the case. This is just a suggestion and if we come to an understanding of that, we may save a lot of time.

The COURT. I take it this question is directed to the question of integrity?

Mr. FLEISCHMAN. No, it is not.

The COURT. What is it directed to? Is the question as to the reputation of Arner & Company for selling the drug?

Mr. FLEISCHMAN. We can eliminate that part of it and I can withdraw the question, if Mr. Doran will say that we used every possible precaution required by law after we got this bottle from Arner & Company, that we didn't do anything except what the law requires and that is all.

The COURT. Let us not deal in generalities. The question, unless withdrawn, is as to the reputation of Arner & Company. As far as I see, it goes only to the question of intent and if not an element in this claim, it seems to me to be immaterial. If it has some other purpose I would like to know it to pass upon it.

Mr. FLEISCHMAN. May we approach your Honor?

38 (Discussion off the record.)

The COURT. I will sustain the objection.

Mr. FLEISCHMAN. No exception to that, your Honor.

By **Mr. FLEISCHMAN**:

Q. Now, so far as you are concerned, you don't know of any test that was made on this digitalis?—A. Not by my direct knowledge, no.

Q. What you saw at the time you got this bottle was a bottle in form about the same required by the Government for digitalis tablets?—A. Yes.

Q. Now, did you know at any time that that digitalis had come from Arner & Company?

Mr. DORAN. I object to it as immaterial and irrelevant, where it came from.

The COURT. I will receive it.

A. I answered that question. I did not, about this specific product. I did know that a great many of the products of the Buffalo Pharmacal Company came from Arner & Company some years ago—

Q. Did you know about this one?—A. Not specifically about this particular product, no.

Q. Now, did you go to any doctor to whom the product had been sold that came from Arner & Company, from any source, to determine whether there were these digitalis tablets out?—A. I am not sure that I understand the question, Arner & Company do not ship anything direct as far as I know.

Q. Did you go to any doctor to whom the Buffalo Pharmacal shipped the product of Arner & Company?—A. No.

Q. You mean you were not sent to Dr. Tagett?—A. I called on other doctors.

39 Q. How many doctors?—A. Oh, I suppose several dozen on that trip.

Q. We can limit that to say twenty-four?—A. Well, I don't know exactly.

Q. Roughly?—A. To a number of doctors.

Q. Did you test the product that you got from the other doctors, product of the same kind, from the same place?—A. Are you speaking of the Buffalo Pharmacal products now?

Q. Yes, sir, that is all I am talking about.—A. All the samples that I collected at any place was transmitted to the Administration for examination.

Q. And you figure that was approximately 24?—A. Excuse me, I think that is a misunderstanding, I think I included other samples from other firms besides the Buffalo Pharmacal Company.

Q. Will you please list them for the purpose?—A. There were not 24. The Buffalo Pharmacal—

Q. You had access to the books of the Buffalo Pharmacal Company to find out where they sell any piece of merchandise of theirs?—A. Yes.

Q. You, therefore, had access to it and looked it over to find out how many doctors they sold digitalis to as contained in Exhibit Number 3, didn't you visit those other places?—A. No, sir, I did not, I hadn't any reason.

Q. No, did you visit them or not?—A. I wasn't taking a list of doctors grouped from the Buffalo Pharmacal Company in visiting them. I know of a great many doctors in our territory that already purchased digitalis, products of the Buffalo Pharmacal Company—

Q. You are employed by the United States?—A. Yes.

Q. In a very important division of the Department of Agriculture?—A. Not now.

40 Q. Well, at that time, it was?—A. Yes.

Q. And you found in the possession of the doctor a digitalis that was about half the strength, or a little less than

half the strength than the bottle label said it contained?—A. I know nothing about it.

Q. There came a time that you learned about it?—A. Yes, sir.

Q. When you found that condition to be what it was, didn't you want to know who else had gotten those tablets?—A. Excuse me, I follow the instructions in making these surveys and I didn't know for a long time after that there was any reason to suspect it particularly.

Q. Well, did you buy any more from other doctors the same as Tagett?—A. He would get the sample digitalis in this type of—

Q. A bottle containing a screw top?—A. What we call a screw cap.

Q. What else goes in it, you see some cotton inside of it?—A. Yes.

Q. And that is all?—A. Yes, sir.

Q. Now, coming down to the tablets of the Cascara here, do you know anything about Dr. Hinkel?—A. I have seen the name, sir.

Q. You have seen it all the years that you have been in the business?—A. I have, a great many times.

Q. You don't know if the man is alive or not, but that is the name of a physician who at one time prescribed a certain pill or tablet or disc known as cascara?—A. I simply know there was a product made, many years on the market, that was called "Hinkel's pills."

Q. And the Hinkel pills as you know, from the time you went into the Department, have contained strychnin?—A. In the early years, yes.

41 Q. What early years?—A. I think until, I am not sure when the revision of the National Formulary occurred, but several years ago.

Q. And when you got into the Department, you knew Dr. Hinkel's pills contained strychnin?—A. They contained strychnin.

Q. And for many years after that?—A. I cannot say how many years, but when I came there they did.

Q. Do they contain strychnin now?—A. The National Formulary—

Q. Do they contain strychnin now?

MR. DORAN. I object to Counsel interrupting the witness.

Q. Do you understand me?—A. I am not sure.

Q. If I mislead or break in, will you please stop me?—A. Yes, sir; the correct product now labeled as Hinkel's does not contain strychnin.

Q. Then it is not Hinkel's—A. I couldn't say as to that.

MR. DORAN. I object to that as argumentative.

MR. FLEISCHMAN. I think that is admissible.

Mr. DORAN. This witness does not claim to be an analyst.

The COURT. He claimed when he came into the Department, that Hinkel's pills contained strychnin?

Mr. DORAN. Yes.

The COURT. How does he know that? The question is now, do they now contain strychnin? If he has knowledge, he may answer.

Mr. DORAN. All right.

The WITNESS. I did answer that the National Formulary for Hinkel's pills does not.

42 Mr. FLEISCHMAN. And then I tell you, it is not the Hinkel pill.

Mr. DORAN. I object.

The COURT. Sustained. That is argumentative.

By Mr. FLEISCHMAN:

Q. Do you know that solution, the liquid solution of Hinkel's cascara?—A. I have seen the name in catalogs, I don't recall the sample now.

Q. Did your investigation, don't you find out whether the Hinkel liquid solution contains strychnin or not?—A. If in the calls I encountered any product containing strychnin with that on the label, I would get a sample for analysis.

Q. Did you?—A. I don't recall if liquid or pills.

Q. Do you have a tablet as distinguished from the pill?—A. Yes, but I don't recall specifically, but in the early years, it must have.

Q. It contained strychnin?—A. Yes, sir.

Q. Now, of course, there is a great deal of difference between a pill and a tablet?—A. There is a difference in the physical—

Q. No, no, not the physical make-up. Do you know of any other difference in the making, in the compounding?—A. The ingredients?

Q. Yes.—A. I don't think so, except the form of manufacturing.

Q. Do you know anything about it personally as to the compounds, we will say, of the Norwich Manufacturing Company, and in this case whether their pills use—the different pills and tablets and liquids—where it is permitted to have the strychnin?—A. They are a large concern—

43 Q. The largest in the world?—A. I don't think so.

Q. Have it your own way then.—A. I don't think it is.

Q. At any rate, you know, do you not, that the pills or tablet refer to cascara?

The COURT. What are they, pills or tablets?

Mr. FLEISCHMAN. They are tablets.

Mr. DORAN. Marked tablets?

Mr. FLEISCHMAN. Cascara tablets.

The WITNESS. Yes.

Q. Not pills?—**A.** The label on the bottle, tablets?

Q. Manufactured by the Norwich Manufacturing Company?

Mr. DORAN. I object to this as immaterial.

The COURT. I will receive it. I would like to know the difference there is between the pills and tablets.

Mr. DORAN. We expect to go into that with the analyst. He did not make the analysis.

The COURT. All right.

Mr. FLEISCHMAN. These are tablets.

Mr. DORAN. That is your statement.

Q. What is it, a tablet or a pill?—**A.** It is a tablet.

Mr. FLEISCHMAN. Now we know it, we know now, it is a tablet.

Mr. DORAN. I think counsel's statement should be stricken. He is not testifying.

The COURT. This gentleman who is the inspector has said they are tablets. Now, I assume that he knows the difference between the tablet and the pill; and if he doesn't I think we ought to—

44 **Mr. DORAN.** The witness was not called for any other purpose except as the inspector who picked them up. I have not qualified him otherwise. He is not an expert.

The COURT. Does the distinction between pills and tablets require the service of an expert analyst?

The WITNESS. I am not one.

The Court. I am not asking you that. Can you, an inspector in the Food & Drug Administration, tell the difference between them by an examination?

The WITNESS. From their physical appearance.

Q. Then it does not require the services of an analyst?—**A.** No.

Q. Then these are tablets?—**A.** Yes.

Q. Now, you are acquainted with the bible of your profession, the National Formulary?—**A.** Yes.

Q. And they describe in the index what are pills and what are tablets, so there is a difference between them, isn't there?—**A.** Yes.

Mr. DORAN. I object to the improper cross-examination.

Mr. FLEISCHMAN. I am making him my own witness.

The COURT. I will receive it. I won't say what I will do if it goes farther.

Q. Assuming that these tablets which you picked up in Homer City, Pennsylvania, contained Strychnin, that was on the label?—**A.** Yes.

Q. That told you the truth what it contained?—**A.** Yes.

Q. It couldn't be misbranded?

Mr. DORAN. That is objected to, that is a question of law and argumentative.

45 **The COURT.** Reframe your question and instead of using the word "misbranding," ask him if the label told what was contained in the pill.

Q. Did you hear the question of the Judge?—**A.** Yes.

Q. Did the label correctly describe the make-up of these tablets which you called "Dr. Hinkel's tablets"?—**A.** The label stated that the tablets contained strychnine sulphate.

Q. And it does?—**A.** I didn't analyze it.

Q. If the label told us anything that this tablet contained, that is the truth, isn't it?

Mr. DORAN. I object to that as calling for a conclusion.

The COURT. It is quite manifest, I think.

Mr. FLEISCHMAN. I will withdraw the question if you desire.

Mr. DORAN. I may say, the sole charge in respect to this product which is labeled as a Hinkel tablet in the National Formulary it does not contain that ingredient.

Mr. FLEISCHMAN. We are not charged with adulteration, they have dismissed that charge. What they are saying that we misbranded it.

The COURT. He already said that the label told correctly the contents of the bottle. The question of whether the truth or not is superfluous. I will sustain the objection.

Mr. FLEISCHMAN. Do doubt about it. Thank you, that is all.

The COURT. We will recess until two o'clock.

(Recess until 2:00 o'clock P. M.)

46 After recess, 2 P. M.

ARTHUR W. MUNN, called as a witness on behalf of the Government, and sworn, testified as follows:

Direct Examination by **Mr. DORAN**:

Q. Mr. Munn, where do you live?—**A.** Buffalo, New York.

Q. Your name is?—**A.** Arthur William Munn.

Q. What is your business?—**A.** I am a receiver and shipper of the Buffalo Pharmacal Company. I am also treasurer and have complete charge of the plant in the absence of Mr. Dotterweich.

Q. When was that corporation organized, Mr. Munn?—**A.** I think our organization was incorporated in 1937, I believe.

Q. And that is a New York State corporation, is it not?—**A.** Yes.

Q. Under the corporate name of the Buffalo Pharmacal Company, Inc.?—**A.** Yes.

Q. You say you believe it was incorporated in 1937?—**A.** Yes.

Q. You have been the treasurer?—**A.** Yes.

Q. How long have you been the treasurer?—**A.** Since our company started, which I believe was in the fall of 1937.

Q. And what is the business of that corporation, what has been its business since it was incorporated?—A. The buying and selling of drugs.

Q. Buying and selling of drugs. As I understand it, your concern, since it has been organized, the company has not done any manufacturing, is that right?—A. Yes.

Q. What is your company known as, dealer or jobber, or what?—A. I would say a jobber.

47 Q. Now, you know of course, Joseph Dotterweich, who is one of the defendants in this proceeding?—A. That is right.

Q. You are also related to him?—A. Yes.

Q. A brother-in-law; is that right?—A. Yes.

Q. Mr. Dotterweich, the defendant, he is connected with that company, the Buffalo Pharmacal Company, Inc.?—A. Yes.

Q. And he has been since it was incorporated in 1937?—A. Yes.

Q. What is his official capacity with it, I mean by that, is he president, manager or what is he known as for the conduct of that business?—A. President and general manager.

Q. President and general manager? And he has been general manager since the corporation began doing business after its incorporation in 1937?—A. That is right.

Q. And he during that period and up to the present, has given his full time to the company?—A. Yes, sir.

Q. And has been there at the place of business during the usual business hours of the day throughout that period?—A. Many times the business takes him out of town.

Q. Except on occasions when business calls him out of town, that is the fact, isn't it?—A. Yes.

Q. Now, you say in addition to being the treasurer of the company, you have been how employed, in what way?—A. Receiver and shipper.

Q. That is what you are known as?—A. I taken complete charge of the receiving and shipping end.

Q. Was that so in October, 1939, and January, 1940, Mr. Munn, that was the same?—A. Yes.

48 Q. And under whose supervision did you perform your duties as receiver and shipper for that company?—A. Mr. Dotterweich.

Q. And it is a fact since the company has been organized, and you have been with it, he is the only person from whom you take orders and who supervises your work?—A. Yes, sir.

Q. Now, I take it that you have had during that period of time since you have been connected with the company, which includes, of course, I take it, the month of October, 1939 and January,

1940, a certain general policy in the way your shipping is handled, is that correct?—A. That is true.

Q. And is it a fact that that general policy was outlined to you and you have followed it during that period under the direction of Mr. Dotterweich?

Mr. FLEISCHMAN. We object to "general policy." This is a criminal case involving an individual, and the general policy has no place in it.

The COURT. I think it has. It is upon you to show this particular shipment.

Mr. FLEISCHMAN. All right.

Q. I believe you were served with a subpoena *duces tecum*, to produce certain records of the company with respect to shipments of digitalis and cascara?—A. Yes.

Q. Have you those records here?—A. Yes, I have duplicates of them.

Q. Let me see them [witness handling records to Mr. Doran].

Q. Mr. Munn, was there shipped by the Buffalo Pharmacal Company, Inc. on or about January 9, 1940, a quantity of digitalis tablets to Dr. H. J. Tagett of Rock Creek, Ohio?—A. Yes.

49 Q. That shipment moved out from Buffalo, New York to Rock Creek, Ohio, is that a fact?—A. That is right.

Q. By means was it shipped?—A. Could I see that?

Q. Sure, you can refresh your recollection from the records.

Mr. FLEISCHMAN. Of course, that has all been stipulated.

Mr. DORAN. Yes; but tying it down to the individual. I may say that the stipulation does cover the confession that the Buffalo Pharmacal Company shipped them in interstate commerce from Buffalo to Rock Creek, Ohio. My only point in calling this witness is to connect the individual defendant with the corporation defendant. That is my only point. I don't want to prolong it.

The WITNESS. Yes, it went out by parcel post C. O. D.

Q. On or about what date?—A. January 9, 1940.

Q. Did you personally have anything to do with that shipment, Mr. Munn?—A. Yes, I did.

Q. And in what way, I mean by that, did you supervise the packaging in preparation in the packaging department?—A. The packaging and parcel post end of it.

Q. And in doing that did you act under the supervision and direction of Mr. Dotterweich?

Mr. FLEISCHMAN. I object unless it applies to this specific item and within the knowledge of this man, of this specific man. I am preserving my right on this record. This is a transaction that took place two years ago.

The COURT. I would like to hear your argument on that without the presence of the jury.

50 **Mr. DORAN.** All right, your Honor. I think perhaps we could do it right now.

The COURT. The jury is excused for five minutes.

(Jury excused.)

The COURT. I will see what the facts are. In regard to this other matter, I see no alternative except to allow the Government to demonstrate on the general policy here of instructions to the employees and particularly to the shipping man, and then if there is some question of lack of responsibility upon the part of the individual defendants, that is a matter of defense, if you can show it absolves the particular transaction from the general policy. I know of no other way.

Mr. FLEISCHMAN. Will your Honor be kind enough to grant me an exception?

The COURT. Yes. I never had one of these violations tried before me.

(The jury returns to Court Room.)

Mr. FLEISCHMAN. I take exception, it calls for a conclusion.

The COURT. I have previously ruled you cannot show the general policy. I am now ruling you can show that and then ask the question similar to that.

Mr. DORAN. Very well.

Q. Mr. Munn, was there during October 1939, and January of 1940, a general policy or routine of business with respect to shipments made by the Buffalo Pharmacal Company, Inc.?

Mr. FLEISCHMAN. Object to on the grounds it calls for a conclusion.

51 **The COURT.** Ask him what, if any, instructions were issued by the individual defendant with reference to the shipments, whether a general policy or not:

Mr. DORAN. I thought you said I might go into the general policy.

The COURT. Yes, ask him what the instructions were and then demonstrate by facts if a general policy.

Q. What instructions did you receive with respect to the handling of shipments made by the Buffalo Pharmacal Company, Inc.?—**A.** Well, if I understood it correctly, I brought the shipping idea to the Buffalo Pharmacal Company myself, I brought into the shipping room various plans in shipping by parcel post, and I more or less created a system of parcel post.

Q. That is, you had some sort of system of your own, is that the idea?—**A.** Yes. Formerly I had been a shipping clerk.

Q. You had been a shipping clerk for sometime?—**A.** Yes.

Q. You were with another concern before this one, is that right?—**A.** Yes.

Q. Let us go back to your original employment with the Buffalo Pharmacal Company, Inc., did you go there at the request of someone that—

Mr. FLEISCHMAN. May I raise this objection? I want to protect the rights of the defendant as well as this witness. If the argument of the District Attorney is correct, then I shall instruct this man that any answer he may make might incriminate him.

Mr. DORAN. That is not your prerogative to inject that in this case.

52. Mr. FLEISCHMAN. You can instruct the witness if he wants to take advantage of that.

Mr. DORAN. You have no right to do that, and I object to it, it is not privilege.

Mr. FLEISCHMAN. Am I right or wrong on that? I think it is my duty to do that.

Mr. DORAN. It is highly improper.

The COURT. You are not here representing this witness, now on the stand. If anyone's duty it is my duty.

Mr. FLEISCHMAN. I ask your Honor to do it, I ask your Honor to instruct this man, in view of the argument.

The COURT. As I said, you ought not to worry about it, but that I ought to.

Mr. FLEISCHMAN. All right.

Q. The question was, did anyone request you to go with the Buffalo Pharmacal Company, Inc.?—A. No, I joined them.

Q. Well, you must have talked to someone when you joined the organization of the Buffalo Pharmacal Company, Inc.?—A. Yes.

Q. With whom did you talk?—A. To Mr. Dotterweich.

Q. Now, I ask you the question, was it at his suggestion that you went with that company?—A. That is right.

Q. All right. And you started in with the company as shipping and—as the shipping clerk, is that what you are now?—A. That is right.

Q. Now, this was a completely new business enterprise, wasn't it, on the part of that corporation?—A. Yes, sir.

Q. Did you discuss when you went with the Buffalo Pharmacal Company, Inc., with Mr. Dotterweich on the shipping routine and shipping policy?—A. Yes.

53. Q. You did?—A. That is correct.

Q. And did you both discuss that, that is, you and Mr. Dotterweich, the routine or policy that was to be followed in the course of the conduct of the business of that corporation in so far as shipping was concerned?—A. Yes.

Q. You did that?—A. Yes:

Q. Now, I take it after the time you originally went with the company, you say it was in 1937?—A. Yes, 1937, I believe.

Q. From time to time thereafter, I take it, did you also discuss later the shipping routine or method and so on with Mr. Dotterweich?—A. Only on very important heavy shipments. The smaller ones I handled all myself.

Q. Later on, that is the only way you discussed it, on later occasions, is that right?—A. Yes.

Q. From time to time was there any change ever made in the general routine or method of handling shipments?—A. Yes, we made some improvements.

Q. You made some improvements, is that right?—A. That is correct.

Q. And I take it that at the time, those improvements were made, or on or about those times, you discussed the matter of those improvements with Mr. Dotterweich, did you not?—A. That is right.

Q. And I take it that some of the improvements were carried out and some may not have been, is that the fact, or what was the fact?—A. It was the fact.

Q. So far as your duties were concerned right straight through from the time you became connected with this company in 1937, under the circumstances that you have mentioned, through 1939

and 1940, all of your duties as shipping clerk, we will say, 54 or the shipper for this corporation, were directly under the supervision and charge and authority of Mr. Dotterweich, is that right?

Mr. FLEISCHMAN. I object on the ground it is leading, secondly it is suggestive and third, it is incompetent, irrelevant and immaterial.

The COURT. First, in regard to the leading, I think he had the right to lead him.

Mr. FLEISCHMAN. You are holding not as against the corporation, that would be correct if against the corporation. You are now talking about the individual.

The COURT. I don't think that changes it. I will overrule you.

Mr. FLEISCHMAN. Exception, please.

Q. Ever since you came with the Buffalo Pharmacal Company, Inc., in 1937 and right down through 1939 and 1940, did you act under the direction and under the authority of Mr. Dotterweich as general manager of this corporation, in the performance of your duties?—A. Of my shipping duties?

Q. Yes.—A. No, not on all occasions.

Q. Well, generally speaking—do you mean by that, I take it by that answer you mean, and see if I am correct about it, that there were times shipments were made by this corporation that

you might not have personally talked to Mr. Dotterweich about, is that right?—A. No, I mean by that many times Mr. Dotterweich probably was out of town ten days or two weeks, and I took it upon myself to ship it my own way, I handled things in my own way in shipping.

Q. You mean by that on some occasions when he was out of town you were in charge of the shipping facilities or routine?—

A. In charge of the plant.

55 Q. That is, the plant for this company, is that right?—

A. Correct.

Q. Now, you say this shipment of digitalis went out on or about the 9th day of January 1940, is that right?—A. That is right.

Q. And the shipment of cascara went out on or about what date?—A. October 2, 1939.

Q. That shipment of cascara, by the way, was to whom?—A. To Dr. M. M. Palmer, 49 Elm, Homer City, Pennsylvania.

Q. On those days, Mr. Dotterweich was the general manager or the head of the employees of this company?—A. I don't remember, that is quite a time back.

Q. Was he the general manager at the time, you recall that?—A. Oh, yes, he was the general manager.

Q. And he was the person in charge of the employees and the only person over the employees of the corporation at that time, isn't that the fact?—A. In those particular days?

Q. During January 1940 and October of 1939.—A. Yes, sir. Mr. DORAN. You may ask.

Cross-examination by Mr. FLEISCHMAN:

Q. Well, young man, can you tell this jury and the court, whether or not you made the shipment in October or were you out of town, will you swear you did do that?—A. No.

Q. So it could be a third person who shipped these particular shipments?—A. Yes.

Q. If Mr. Dotterweich was away and you were indisposed, it might be somebody else?—A. Yes.

Q. There is always somebody else to take our place?—A. Yes.

56 Q. So you have no way of telling about these particular shipments, have you?—A. No.

Q. Tell me this, Mr. Munn, do you have any pills in your place for sale?—A. No.

Q. Did you ever see any pills in your place for sale?—A. No, sir.

Mr. FLEISCHMAN. That is all.

Mr. DORAN. Will you leave this here please? [Indicating record.]

The COURT. What is a pill?

The WITNESS. I am not a chemist.

The COURT. You use the terms "pills" and "tablets," and you understand why I ask you.

The WITNESS. If I may give an opinion, a tablet is a compound powder form which revolves in a machine and is punched out.

The COURT. You mean the different shapes?

The WITNESS. The pill is the size only, proceeding in the ~~same~~ form of putting, I am not sure.

Mr. FLEISCHMAN. Our expert will give you that.

Mr. DORAN. And ours will, too. May I have these two orders marked for identification?

(Two orders marked Government Exhibits 4 and 5 for identification.)

CLARENCE W. GRASER, called as a witness on behalf of the Government, and sworn, testified as follows:

Direct examination by Mr. DORAN:

Q. Your name is Dr. Graser, is that right?—A. Yes.

Q. Are you a physician?—A. Yes.

Q. You live where?—A. In Buffalo.

57 Q. And was there a time when you became an officer of the Buffalo Pharmaceutical Company, Inc.?—A. There was.

Q. When was that, approximately?—A. Oh, in the fall of 1937, I think it was.

Q. And at about the time you became an officer of that company did you talk to any individual about it, or did someone bring it up to you in conversation?—A. Well, Mr. Dotterweich talked to me about it.

Q. You mean Mr. Joseph Dotterweich, the defendant here in this proceeding, is that right?—A. Yes.

Q. What was the conversation?—A. Well, he wanted to start a new drug company in Buffalo, and would be in competition with his own bunch and didn't want to start it under his own name, and asked if he could use mine, feeling that if I consented to that name as president, it would add a little prestige, to the company.

Q. I take it by that he said he would organize a corporation?—A. Right.

Q. Do I understand you correctly, in view of the duties he related to you, he wanted to know if you would act as president of this corporation?—A. Well, nominally.

Q. Nominally, that is what he said to you, is that what you mean by your answer?—A. Yes.

Q. Were you then elected president of that corporation?—A. I guess they just assumed it.

Q. At any rate, you were for how long?—A. Well, we felt there was no difference in whether a doctor's name at the head of the concern or not, so I resigned in January, 1940, I believe it was.

Q. January, 1940?—A. I think it was, yes.

Q. Now, did you personally have anything to do with the active conduct of the business affairs of that corporation?—A. Not one thing.

58 Q. So far as your own knowledge is concerned, who was the person directly in charge of the business affairs of that corporation during the period you were?—A. Mr. Dotterweich.

Q. Joseph Dotterweich?—A. Yes; sure.

Q. The place of business, by the way, was where?—A. 200 Oak Street, Buffalo.

Q. Were you during the period you were president, down to the place of business?—A. I would go in for a visit once in a while and buy a few drugs.

Q. And the physical make-up of the place of business, is it a fact it was on one floor, Doctor?—A. Yes.

Mr. DORAN. You may ask.

Cross-examination by Mr. FLEISCHMAN:

Q. Just one question, Doctor. During the time that you were the president of the company, the corporation did not elect, like the president of the United States, but the directors met and elected you?—A. Yes.

Q. Did anyone ask you to do anything in this corporation that was wrong, or did you ever see anything done wrong?

Mr. DORAN. I object to that.

The COURT. Sustained.

Mr. FLEISCHMAN. Exception.

Q. Did you ever see any compounding of drugs in this corporation?—A. No.

Q. They bought the stuff?—A. They bought it in large containers and packed it in bottles and—

Q. In packages to sell the stuff?—A. Yes; and they sent them out.

Mr. FLEISCHMAN. That is all.

59 SOLOMON M. BERMAN, called as a witness on behalf of the Government, and sworn, testified as follows:

Direct examination by Mr. DORAN:

Q. Mr. Berman, you are employed by the Food & Drug Administration?—A. Yes, sir.

Q. How long have you been so employed?—A. Just ten years.

Q. In what capacity are you employed by the Food & Drug Administration?—A. As a chemist.

Q. And have you been employed as a chemist all during that period of ten years?—A. Yes, sir.

Q. Briefly, what are your duties as such?—A. I receive samples of drugs of all kinds and I analyze them and make a report of my findings.

Q. To the agency that you work for?—A. Yes, sir.

Q. What education do you have in the field of chemistry?—A. I majored in chemistry at the University of Pennsylvania and I was graduated in June of 1931, and since then was continually employed with the Food & Drug Administration, specializing in drugs, pharmaceutical and patent medicines.

Q. Do you have a degree in chemistry from the University of Pennsylvania?—A. Yes, sir.

Q. Have you had any other education or experience other than what you have mentioned?—A. No, sir.

Q. I take it that during the course of your experience, you have analyzed a great number of samples of drugs of one kind or another, is that right?—A. Yes.

Q. Approximately, do you know how many?—A. Oh, several thousand.

Q. I show you Government's Exhibit Number 1, in evidence, and ask you if you saw that at some previous time in the course of your official duties?—A. Yes, sir.

Q. And when did you first see it?—A. Well, I have the inspector's seal here, initialed with the date of November 6, 1939.

Q. And where was it received?—A. Well, I was analyzing at the Buffalo Station of the Food & Drug Administration.

Q. At the Buffalo station or office of that agency?—A. Yes.

Q. In what condition was it when you received it?—A. It was labeled, the bottle was wrapped in cellophane, I believe, with the seal of the Department of Agriculture, bearing Number 78814-D inspector John Faries.

Q. Was it capped?—A. Yes, sir; essentially as it is now.

Q. When you speak of a seal, what kind of a seal?—A. This so-called official seal of the United States Department of Agriculture. On top of that seal is the Federal Security Agency.

Q. What did you do with it after?—A. I made an analysis of it.

Q. What sort of analysis did you make, Mr. Berman?—A. To find out whether it complied with the standard of the National Formulary.

Mr. FLEISCHMAN. I move to strike out the answer, not responsive. He asked him what kind of an examination he made.

The COURT. Sustained.

Q. Let me ask this question. For what purpose did you make your analysis, Mr. Berman?—A. To find out whether it complied with the standard of the National Formulary.

Q. Then tell me if you will, what sort of an analysis 61 you made?—A. I made a chemical analysis for the essential ingredients.

Q. Did you come to a conclusion as to whether or not, from your analysis, as to whether or not the contents of that exhibit did conform to the National Formulary?

Mr. FLEISCHMAN. I object on the ground no proof on the National Formulary. He can say what it contained. It is not for him to say whether it conformed.

Mr. DORAN. That is not so as the Act makes it a necessity for employees of the Food & Drug Administration to test to either the U. S. Pharmacopeia or the U. S. Formulary, which is recognized as the official compendium.

The COURT. It seems to me that the proper order would be to prove National Formulary, and then to have him give his analysis of the contents he found.

Mr. FLEISCHMAN. Then I will withdraw my objection.

Q. You made this analysis on what date, Mr. Berman?—A. On or about November 6, 1939.

Q. Were you familiar with the formulae as it then existed in the National Formulary for Hinkel's pills?—A. I would refer to the text of the National Formulary whenever I would want to know what it was.

Q. Can you find it there [Attorney handing text book to witness]?

Mr. FLEISCHMAN. I take exception if the witness thinks he is going to read about pills. I don't care anything about that. We are dealing with tablets.

Mr. DORAN. I take it that what Counsel is talking about, 62 in that respect is that the article did not purport to be the official article or drug as mentioned in the National Formulary, because the National Formulary after the word "Hinkel," it says "Pills" or uses the word "pills" in that and because of that very technicality that the label in this case called for tablets, and that, therefore, it doesn't purport to be or is not represented to be the official article.

Mr. FLEISCHMAN. Not at all.

Mr. DORAN. The label itself, under the charge, and under our claim, it purports to be and represents to be the official article. We submit and we believe we are right about it, that merely because one shipper may upon his label use the word or term "tablet" as compared to "pill" that does not save him from the

provision of this statute, and there is a very definite regulation in that respect.

The COURT. Where did this text get its authority?

Mr. DORAN. From the Act of Congress.

The COURT. And does the act give them the authority to prescribe the regulation?

Mr. DORAN. Yes.

Mr. FLEISCHMAN. I am disputing only the fact that it says Hinkel's pills. We say on this bottle is exactly what is in this bottle, no mis-branding. We are talking about tablets.

Mr. DORAN. That is exactly what I said. You use the word "tablet" instead of "pill." We say it is a distinction without a difference.

The COURT. I don't know if it is or not.

Mr. FLEISCHMAN. Why not put an expert on the stand to tell us? I have my expert here for that purpose. He can use our expert.

63 **Mr. DORAN.** No, we will go along.

Mr. FLEISCHMAN. You cannot.

Mr. DORAN. What is your objection?

Mr. FLEISCHMAN. The objection I am raising is that in discussing the question of Hinkel pills—

The COURT. I am going to overrule the objection at this time and admit this evidence to what the National Formulary is. If some other evidence convinces me otherwise and this does not apply here, that goes to the question of whether or not they sustained the burden of proof.

Mr. FLEISCHMAN. That is all right.

Q. Do you remember the question?—**A.** I think I do.

Q. What does the National Formulary provide as to the detail of your analysis with respect to the article, Hinkel pills?—**A.** Do you want me to read that?

Q. Read it; yes.—**A.** "Extract of cascara sagrada, aloin, resin, podophyllum, extract of belladonna, strychnin sulphate"—**C.** I beg your pardon.

Mr. FLEISCHMAN. What is the strychnin you were just reading?

Q. What do you want to say about that?—**A.** It was unintentional.

Q. Go ahead.—**A.** I had no intention of saying strychnin sulphate. "Oleoresin of ginger, glycyrrhiza and glucose." What I just gave was the National Formulary formula for that preparation as of January 1, 1939.

Q. As I understand there was a change made as of January 1, 1939, with respect to Hinkel pills?—**A.** Yes.

Q. What was the change?—**A.** The strychnin sulphate was removed from the formula.

64 Q. That deletion and removal, this ingredient removed from the formula for Hinkel pills, it was deleted as of what date?—A. January 1, 1939.

Q. Now then, you made your analysis, you say, that portion of that exhibit for the purpose of determining whether or not the contents did comply with the formula as it existed on that date?—A. Yes.

Q. What did you find?—A. I found it was a pink-coated tablet containing essentially strychnin sulphate, extract of belladonna, ginger, aloin, cascara and a podophyllum.

Q. Did you reach a conclusion as to whether or not from your analysis, as to whether or not it complied with the Formulary, with the Official Formulary as of the date of your analysis?—A. Yes.

Q. What was it?—A. That it did not comply.

Q. In what respect?—A. Because it contained strychnin sulphate which is not in the formula.

MR. DORAN. You may examine.

CROSS EXAMINATION BY MR. FLEISCHMAN:

Q. Mr. Berman, did you know Dr. Hinkel in his lifetime?—A. No, sir.

Q. But in the years that you have been connected with the department you came to know what the Hinkel pills are?—A. Only by reference to the formula.

Q. And when you begged our pardon, you were reading from the National Formulary as it was from 1939?—A. Yes.

Q. Can you tell us how long back prior to 1939 the Hinkel pills contained what it read before you begged our pardon?—A. No.

Q. And if I said 50 years, would you have reason to dispute it?—A. No.

Q. Will you show me the book from which you read, and what you read?—A. [Witness showing book to attorney.]

65 Q. When you were reading this at what point was it that you managed to tell us about this strychnin?—A. [Witness indicating.]

Q. Strychnin isn't in this book?—A. It is in a lot of places in the book.

Q. And this particular thing about Hinkel, was the strychnin in there when you read from the book?—A. I beg your pardon for making the error.

Q. No, no.

MR. DORAN. Isn't it in the supplement there?

Q. You weren't reading from the book then, you were telling us something in your mind. It wasn't the book. The book doesn't

contain strychnin in there.—A. It contains strychnin in a lot of places and right here, too, I think.

Q. No, no. We are talking now about a drug and that is cascara Hinkel pills that you have before you now. That contains strychnin in there?—A. Strychnin sulphate.

Q. And why you stated that was, because you had been reading it for years?—A. No; absolutely not.

Q. Why did you say strychnin and then "I beg your pardon"?—A. I said it is in the book in a lot of places, but I shouldn't be reading that line.

Q. You mean you ought to strike it out?—A. There is no one able to strike it out.

Q. You don't say then to strike it out?—A. In my copy, it is stricken out.

Q. But not this copy that you have here?—A. Yes; it is stricken out.

Q. Is it? Let me see. You don't mean it is stricken out. There is something, it says "1939, Supplement No. 13," and that is all it says. It doesn't say to strike out the strychnin. It means you know it.

66 The COURT. That is an old book, isn't it, that is prior to the 1930 regulations?

The WITNESS. These were all printed in 1936, and the supplement corrected it.

The COURT. In other words, the supplement brought the book up-to-date?

The WITNESS. Yes.

Q. Does it say that brought it up-to-date?—A. I am not finding any fault with you, but just want to know how long the strychnin was in there.—A. I will give you that information in just a moment.

Q. Are you looking at the index, young man?—A. No.

Q. No objection, but just what you are reading from.—A. I haven't read from anything else. As a matter of fact, the information that I am looking for isn't where I expected to find it.

The COURT. We will take a five-minute recess.

(Short recess.)

Mr. FLEISCHMAN:

Q. Mr. Berman, do you remember the last question?—A. No, sir; I do not.

Q. What is it you are looking for there now?—A. This change. It says "Supplement 3, page 4," that is what I am looking at right now.

Q. You have the supplement now?—A. Yes.

Q. It is pasted in the book?—A. Yes.

Q. That is the same book, I take it, that I have, except your supplement is pasted in, it has the supplement of the National Formulary, the sixth edition, 1938!—A. Supplement 3, page 4.

Q. Is that the same one you have there?—A. Yes.

67 Q. Now, will you look at that index in the book you have before you, which is now known as the Official document, look at the index and turn to "Pills," will you, and see whether you can find my Hinkel pills?—A. Yes; on page 289.

Q. 289, is that right?—A. Yes.

Q. Now, there is a long list of pills in that book, is there not, say ten on the first line, page 289 of that book, beginning with "Aitken's pills," is that right?—A. I don't know.

Q. Look where it begins with pills, page 286 in the index.—A. Not very easy to find, maybe more than one name for pills.

Q. Not asking you that. We are reading from the same book, and this is where the pills begin, page 286, and the different kinds of pills, is that right?—A. There might be, not necessarily.

Q. That is the book. I am asking you to read from the books, from there.—A. The names?

Q. No, do you find that I am correct in reading this to you?—A. I don't know what you are reading.

The COURT. Is there an index, and if so, are the pills indexed, and if so, what page?

The WITNESS. I have given page 289 for Hinkel's pills.

Mr. DORAN. I suppose the book speaks for itself.

Mr. FLEISCHMAN. There is the point.

Q. I say there is an index in the National Formulary for pills, is that right?—A. Yes; that is the page for the pills.

Q. Of the different kinds of pills?—A. Yes.

68 Q. Will you turn and find me, if there is an index for the different kinds of tablets. Take a look at the tablets.—A. Yes, there are.

Q. So that your index refers to tablets and pills and gives you the name and the page where you will find it, is that right?—A. Yes.

Q. Now, in looking for a certain tablet you would look in the index to see if given by the National Formulary?—A. Yes.

Q. And you look for pills, look at the same index for the pills?—A. To some extent, not always necessary.

Q. You carry that in your mind, but a poor fellow like me, I would have to use the index?—A. I suppose so, I don't know.

Q. Now, do you know where Hinkel's pills or tablets, now that you have read the book, do you know what constitutes the Hinkel pill?—A. Yes; I read the formula.

Q. And if you remove a certain portion of the formula it is a different pill, might be something like a Berman pill, if you remove something?—A. I don't know.

Q. Well, you are the chemist. Let me put it this way: Assuming that you removed from a certain drug, an important part of it as originally prescribed by the doctor, does it continue on and have that same name?—A. I don't know about that.

Q. But the Government still calls it the Hinkel pill?—A. I have nothing to do with it.

Q. You are in the Chemistry Division?—A. Yes.

Q. Does it call it a Hinkel pill?—A. I have one formula given to me. That is the Hinkel pill, that is the formula.

Q. Look at the bottle. This is the label. Will you tell us whether this label on here, that is the label coming from that bottle, does it conform to the requirements of Hinkel's tablet?—

A. Not in my opinion.

69 Q. Why?—A. Because it contains strychnin sulphate.

Q. Whether it does contain Hinkel's sulphate in that bottle, too?—A. If you mean strychnin sulphate—

Q. Don't you find the strychnin sulphate?—A. Yes.

Q. So that the label correctly describes—

Mr. DORAN. I object to that.

The COURT. Perhaps you can get the same reply you want by using another word.

Q. Assuming you made an examination of this bottle and found the strychnin in there and assuming this label came from this bottle, does it correctly describe what is in this bottle?—A. No, sir.

Mr. DORAN. I object to the form of that question, because that isn't the charge here.

Mr. FLEISCHMAN. He says not.

Mr. DORAN. It purports to represent the official article, with the contents and ingredients not in the formula.

Mr. FLEISCHMAN. If it said castor oil on it, not misbranding?

The COURT. I think the chemist can answer if that label correctly describes it, what is in the bottle.

Mr. FLEISCHMAN. That is right.

The WITNESS. I don't feel competent to answer that question. As an analytical chemist, I don't feel competent.

The COURT. The label, does that describe the contents?

The WITNESS. There is a number of words here, some of which I can check and some of which I cannot.

The COURT. I see.

70 The WITNESS. My analysis is in compliance with the active ingredients. I would have to check those against the Formulary.

Q. Do you mean you haven't got with you the slip which will tell you just what you found when you analyzed the tablets?—A. I should say that the list of ingredients mentioned here—I would say they were all present.

Q. Is there anything at all present not on there?—A. Yes, the coating is not specified.

Q. You mean if sugar coated or plain?—A. Well, that is partly indicated here with initials.

Q. You mean it didn't spell it right out?—A. No, I would say that is—

Q. All right, we will cut that out. Is there any difference to you?—A. No.

Q. So what you found in your assay of that, not contained in the label?—A. No, I said this list of ingredients, the cascara and so forth, there are some more on the label.

Q. That is what I want to know.—A. "Tablets, cascara compound, Number 2, S E Pink." (Hinkel).

Q. Isn't that it?—A. Not in my opinion.

Q. What do you mean by that?—A. The formula for Hinkel does not include the strychnin sulphate.

Q. You are calling your present pills, the Hinkel pill with the strychnin out; you would call that the Hinkel pill?—A. Yes.

Q. And in 1939 if it had the strychnin in, would be a Hinkel pill, is that right?—A. No.

The COURT. 1938.

The WITNESS. Yes.

Q. So that in 1938, by some legislation, it became something that it was not in 1937?—A. A change was made,

71 Q. And not what you have there is what we now call the Hinkel pill?—A. No, I don't call that the Hinkel pill.

Mr. FLEISCHMAN. All right, that is all.

Redirect examination by Mr. DORAN:

Q. You know what the National Formulary is?—A. Yes.

Q. Tell us what it is, to have the jury know.—A. I don't think I am speaking with full expert knowledge.

The COURT. I don't know what the National Formulary is; I never heard about it until a couple of weeks ago. We want you to tell what it is, where does it get its authority and what do you know about it?

The WITNESS. There are two so-called Official Compendiums of drugs, one is known as the U. S. Pharmacopeia, and the other is called the National Formulary. Both of them list drugs that could be found in natural vegetable drugs, drugs that can be manufactured in the mixtures of the two. Sometimes they consist of only one single material and others are very complex. The

National Formulary contains a number of these drugs, that is, the individual drugs and mixtures, which are considered to be useful therapeutically. All in there are used by physicians in the treatment of various diseases and also in diagnosing diseases. The National Formulary is somewhat different from the Pharmacopeia, contains a considerable number of drugs and mixtures of drugs which are similar to the doctor's prescription and they are intended for the treatment of some specific ailment, and in contrast with the National Formulary that does not go into

72 the therapeutic treatment in great detail. There is the great difference between the Pharmacopeia and the National Formulary, as far as the book is concerned.

Q. Where the National Formulary come from, how is it made up?—A. The National Formulary is put out under the supervision of the American Pharmaceutical Association. That is in contract with the U. S. Pharmacopeia, which is put out under the auspices of the Pharmaceutical Convention, made up of the medical men, the biologists and scientists of different branches, and also members of the Government. The American Pharmaceutical Association undertakes to bring this book out without any profit motive, but purely in the interest of the pharmacists and the physicians.

Q. How is it brought out, how is the material made; is it in conventions and do they have committees?—A. They have had committees and conventions for a great many years, I don't know how many, and I should say approximately every ten years; this particular one was issued in approximately 1936, and the one before that in 1926, and they attempt to put it out at the same time as the Pharmacopeia is issued. It is the sister text. They don't cover exactly the same fields. The National Formulary is considered to be the least important of the two. The number of the therapeutic materials which are not included in Pharmacopeia unit, the Pharmacopeia attempts to restrict itself to the most proven and most modern type of drugs. A number of those not included in the Pharmacopeia are included in the National Formulary. When a number of drugs are found no longer to have much use, which fact is found out by prescription

73 surveys, an action may be taken to exclude that drug or the mixture from the National Formulary, and the Pharmacopeia, and in the case of the particular drug that we are now describing, like Hinkel's pills, such an action was taken several years ago.

Q. How does the change in the National Formulary, the result of which was the deletion of the ingredient strychnin sulphate, how did it come about?—A. As I said they are issued under the auspices of the National Pharmaceutical Association. When the

particular committees have decided to change a formula which I believe in this case it is the toxicity of the preparation, particularly for children who inadvertently get ahold of these nice sugar-coated pills and consume a great number.

Q. I take it then, from your answer, that both the National Formulary and the sister book as you term it, which is the U. S. Pharmacopeia are the sort of bible of the pharmacists and the physicians?—A. Yes; and in addition, sanctioned by the United States Government under the Federal Food, Drug & Cosmetic Act.

Q. It isn't put out by the Government, and the Association so recognizes, but put out by the U. S. Pharmaceutical Association?—A. That is it.

Mr. DORAN. That is all.

Re-cross-examination by Mr. FLEISCHMAN:

Q. Do you know whether or not there can be pills or there are pills out on the market, cascara pills with strychnin?—A. I believe there are quite a number of pills containing cascara and strychnin.

Q. And that is what you have there, cascara and strychnin, is it not?—A. Yes.

Q. And there is no prohibition against its sale, is there?

Mr. DORAN. I object to that.

74 Mr. FLEISCHMAN. They have gone into everything in the world and I haven't objected to it.

Mr. DORAN. I wanted to clear up something that you apparently were creating some misunderstanding, and I object to it, incompetent, irrelevant, and immaterial and improper.

The COURT. You can ship these, of course, in interstate commerce?

Mr. FLEISCHMAN. No objection to that.

Mr. DORAN. The charge is that it was misbranded.

Mr. FLEISCHMAN. You want to get a picture of this. I am being told this thing, that we are entitled to ship in interstate commerce, if it has strychnin in it, all right. There wasn't any talk about children getting ahold of it. I have been using it for 40 years and it is all right. He is talking about misbranding—

Mr. DORAN. He is taking up his summation and I ask the jury to disregard it.

The COURT. Yes.

Q. You have your analysis of this tablet over here?—A. I know where it is.

Q. I want to ask you this; You have analyzed the pill which is the basis of this count in the information, and I want to ask

you whether it contains cascara, one-quarter grain?—A. I couldn't tell without the analysis.

Q. Does it contain cascara?—A. Yes.

Q. Does it contain this aloin?—A. Yes.

Q. Does it contain podophyllum?—A. Yes.

Q. Does it contain extract of belladonna?—A. Yes.

Q. Strychnin sulphate?—A. Yes.

75 Q. Does it contain this oleo ginger?—A. Yes.

Q. That is all it contains. That is what I was reading from, what is on that bottle. Assuming you took this label off, and you pasted on this bottle, would they give you the information that you want to know as to what it contains in here in the way of drugs? Isn't that simple to answer?—A. No; not to me.

Q. Would it be to the jury, would it tell them what it contained if they went out to buy it and looked it over?—A. I don't know, I cannot speak for the jury.

The COURT. The question is, forgetting about the National Pharmacopeia and everything; the question is whether that label does that label tell you what your analysis found?

The WITNESS. Yes, sir; practically the list of ingredients, but it is contradicted by the title, in my opinion. In other words, it is inconsistent.

The COURT. That is, you say the title that they give that "Hinkel" destroys the categorical analysis of the contents?

The WITNESS. I believe it is inconsistent, not destroyed; no, I cannot say categorically. It destroys it, as far as I am concerned.

Mr. FLEISCHMAN. All right; it destroys it as far as you are concerned. Thank you.

Mr. DORAN. That is all.

HERBERT A. BRAUN, called as a witness on behalf of the Government, and sworn, testified as follows:

Direct Examination by Mr. DORAN:

Q. Mr. Braun you are connected with the Food & Drug Agency of the United States Government?—A. I am.

76 Q. And how long have you been connected with the Food and Drug Agency?—A. I have been with the Food & Drug Administration for five years.

Q. For five years?—A. For five years.

Q. In what capacity are you employed by the Food and Drug Administration?—A. I am associate pharmacologist.

Q. What does that mean to us as laymen?—A. It means the study of drugs on animals.

Q. What are your duties?—A. My duties are to assay digitalis, make tests of digitalis, and I work on research and other projects.

Mr. FLEISCHMAN: Talk a little louder, please, Doctor.

The Witness. Certainly.

Q. Speak just a little louder.—**A.** Yes.

Q. When you use the word "assay," you mean the same as tests?—**A.** Tests, yes.

Q. Do I understand you correctly then that during the five years that you have been connected with the Food & Drug Administration as pharmacologist, your work has been confined to tests of this digitalis or the assay of digitalis?—**A.** That is true.

Q. What education do you have?—**A.** I have a Master's degree and the Ph. D., Doctor of Philosophy, degree from the University of Wisconsin. I obtained that in 1930.

Q. Master degree in what?—**A.** In pharmacology.

Q. From what university?—**A.** University of Wisconsin.

Q. And how long did you study pharmacology?—**A.** I studied pharmacology for four years.

77 **Q.** Before you got your degree?—**A.** Yes sir; before I obtained my degree.

Q. Did you have any other education in this field, or does that complete it?—**A.** I have had experience in the field with a large commercial drug house, the Upjohn Company in Kalamazoo, Michigan.

Q. How long with them?—**A.** Three years.

Q. In what capacity?—**A.** As bioassayist and in experimental pharmacology.

Q. Then after you left the Upjohn Company, you went with the Food & Drug Agency?—**A.** Yes, sir.

Q. What is pharmacology again?—**A.** It is the study of the action of drugs on animals, and the action upon different organs, and the action upon the animals in general.

Q. What do you mean when you say "bioassayist"?—**A.** There are a number of drugs we cannot assay by chemicals, by chemical means, and in order to assay them we have to use animal experimentation, and they have to be used for that purpose.

Q. And you call that the biological assay as contrasted from the chemical, is that it?—**A.** That is right.

Q. And digitalis is one of those drugs?—**A.** Digitalis is one of those drugs.

Q. For the information of the Court and the jury, what is digitalis?—**A.** Digitalis is a very common plant, the foxglove, a common ornamental plant.

Q. It is a plant?—**A.** It is a plant; yes.

Q. What do you say about the foxglove, commonly known as the foxglove plant, is it?—**A.** That is right.

Q. And the plant that grows, is that the idea?—**A.** Yes; grows right around here.

78 Q. That is the base of what we laymen have heard of as digitalis, is that what you mean, Doctor?—A. That is right.

Q. Have you completed your experience?—A. I have.

Q. And your educational qualifications?

Mr. FLEISCHMAN. His qualifications are admitted by the defendant.

Mr. DORAN. Thank you.

Q. I show you Exhibit Number 3 in evidence and ask you, Doctor, whether you have ever seen that before?—A. Yes, I have seen this sample before.

Q. Where did you—when did you first see it, Doctor?—A. I saw it March 4, 1940.

Q. Where was that?—A. That was in my laboratory of the Food & Drug Administration.

Q. In what condition was it when you first saw it?—A. It was a sealed bottle bearing the label of the inspector, John Faries.

Q. When you say sealed?—A. The seal was intact, not broken.

Q. Was that seal over a cap?—A. It was over the cap.

Q. Did you then break the seal?—A. I did.

Q. Did you then make an assay or a test of the contents of that exhibit?—A. Yes; I made a test.

Q. And under the Food & Drug Act, you are required to follow a certain prescribed test, are you not, in making your assay?—A. That is true.

Q. And that is what is known as the official test contained in the United States Pharmacopeia, it is not?—A. That is right.

Q. And I take it that you mean by that, that the United States Pharmacopeia provides and states a test by means 79 of which the strength, the quality and the purity of digitalis may be assayed and tested?—A. Yes.

Q. And you followed that test, did you?—A. I did.

Q. Where is the test found, if I may ask, in the United States Pharmacopeia?—A. It is found in the eleventh revision of the United States Pharmacopeia on page 397.

Q. What page?—A. 397.

Q. You followed the test there outlined?—A. Yes.

Q. Mr. Berman said something, said considerable about the National Formulary; you are familiar with the United States Pharmacopeia?—A. I am.

Q. Tell us what that is.—A. I think Mr. Berman already told you it is a compendium or books of drugs. It is mostly the crude drugs, the animal, vegetable and mineral drugs, but there are a few other preparations with an exact digest. The Pharmacopeia is, of course, formulated by the Pharmacopeia Committees. There are a number of them and every ten years they meet and the com-

mittees are composed of physicians and pharmacists, chemists, and biologists. Every ten years they either add to or delete certain drugs which have been important or have become unimportant. In the meanwhile, on this book, every ten years we get a new volume of the Pharmacopeia.

Q. And this volume that you are now working on, at the time you made this test was known as the "Revision"?—A. Yes.

Q. And it came out when?—A. Came out in 1936.

Q. And that with the exception of supplements and changes, is in effect for ten years?—A. Yes.

Q. So that your next book or revision will come out in 1946?—A. Yes; come out in 1946.

Q. Now, this test or assay provided for the United States Pharmacopeia, you say is found on page 397?—A. Yes.

Q. And that is the one you found?—A. Yes.

Q. Does the United States Pharmacopei also contain and provide for a standard of potency for digitalis?—A. Yes; it does.

Q. What is that?—A. It is called the U. S. Standard Reference, or standard powder. It is put out by the Pharmacopeia Committee and it has been analyzed by a number of Pharmacologists and the certain potency has been ascribed to it and this potency is contained in the vial and anyone who is interested in this standard can purchase it.

Mr. FLEISCHMAN. May I suggest that the witness state what is the standard?

Q. Is there in that U. S. Pharmacopeia a provision—you told me the test in there, of a test of the standard of potency, for purity, quality and strength. Is there a standard set forth in this book?—A. Yes; it says that the assay shall construe the requirement for limit of not less than one and no more than 1.1 digitalis unit.

Q. I want to know what is the U. S. P. digitalis unit.—A. That is identical with an international as adopted in 1938 by the permanent committee on biological standardization.

The COURT. What we want to know is what the body described, what they say was the standard.

Q. Are the figures in there?—A. Yes, they are.

Q. Are there any figures in there?—A. The international digitalis unit represents the activity in $\frac{1}{10}$ grain in the international standard.

Mr. FLEISCHMAN. That is exactly what I asked.

81 Mr. DORAN. Let us not have this comment. You know what your rights are here. I submit this comment each time is objectionable.

Q. Now, what is the potency of this digitalis as stated upon the label of that exhibit?—A. It says, "Tablets, digitalis, 1½ grains, 1 U. S. P. digitalis unit."

Q. Now, in your assay or your test, I take it you made your assay or test for the purpose of determining whether or not the contents of that exhibit which you analyzed and assayed were up to that strength?—A. I did.

Q. What did you find as the result of your test, your assay?—A. I found in my assay that it was only about one-half strength. Then I did another assay and then I found it had a potency of about 42 per cent of the labeled strength.

Q. Did anyone participate in this assay or test with you?—A. Yes; Dr. Miller also ran two tests.

Q. Did you sort of run them together, or were they separate?—A. They were run separately, but about one day apart.

Mr. DORAN. That is all.

Cross-examination by Mr. FLEISCHMAN:

Q. Now, Doctor, you, of course, realize that I am not a chemist. The questions I asked of the other witness would indicate that to you without any question. That is a fair statement?—A. Yes.

Q. You are not expected to know the law and I am not expected to know chemistry?—A. Yes.

Q. So you will help me, when I come to a point where I am not correct; you do that. I have no doubt that you will be perfectly fair. Is there in your opinion any test that is a perfect test on the strength of digitalis?

82 Mr. DORAN. I object to that; there is a law prescribed which makes it a necessity as to what test must be followed.

The Court. Overruled.

A. I don't believe there is a perfect test for digitalis.

Q. The test that you were speaking of is known as the "frog test"?—A. Yes.

Q. How long have you been using the frog test?—A. Well, the frog test has been used since 1902—I think it was originated—the frog method of testing.

Q. Am I correct in saying that you have recently discovered that the test is no good?—A. I don't know that.

Q. Is it a good test or not?—A. It is a good test.

Q. Do you know Dr. Gold of Cornell?—A. Yes.

Q. Is he a recognized authority on the subject?—A. Yes.

Q. You have read his books upon digitalis?—A. Yes; I have read some of his articles.

Q. He is a member of this committee that you are talking about to correct this book that you hold on your lap?—A. Yes.

Q. Is it or is it not a fact that he insists that the frog method is no good and that the cat is—

Mr. DORAN. I object to that. I submit there is a proper way of examining.

The COURT. Well, this is cross-examination.

Q. Has there been a different opinion whether or not the frog method produces the proper result or whether the cat method should be used?—A. Not that I know of; no.

Q. Do you mean you don't know about it, Doctor? Am I correct about that? Doctor, this publication known as 83 "Pharmacy in Science," what is it?—A. I never heard of it before.

Q. Do you keep up with the times?—A. I certainly do.

Q. I will show it to you and ask you whether you recognize this by Doctor Gold who is an authority on digitalis?—A. Yes; I know him personally.

Q. Of course, I have no doubt you do. Do you know that magazine?—A. Yes; I have "Science Topics."

Q. Take a look at this "Pharmacy in Science."—A. I never saw it before.

Q. Can you quickly read what purports to be an article by Dr. Gold in this same one, and that is the Dr. Gold we are talking about?—A. [Witness reading magazine article.]

The COURT. Are you finished reading it?

The WITNESS. Yes.

Q. Do you recognize that article that you read by Dr. Gold?—A. No; it is not published by the scientific publications.

Mr. FLEISCHMAN. We offer it for identification.

(Magazine article marked "Defendant's Exhibit A" for identification.)

Q. You mean you don't know Dr. Gold had written such an article?—A. That is for general knowledge, not a scientific article.

Q. You mean that Dr. Gold who is an authority on digitalis and connected with the Cornell University would write in one way and express himself to us fellows in the other way?—A. As far as I know, he has not signed his name to it. Perhaps it is a newspaper item for general consumption.

84 Q. You have a way of checking up with Dr. Gold whether or not that is his article?—A. Yes.

Q. You would be very much interested to know if that article was his, wouldn't you, Doctor?—A. Yes.

Q. You know, do you, who is the head of the New York State Medical Association?—A. I really don't know that.

Q. Do you know Dr. Pidolski?—A. No.

Q. You don't know he is the president of the New York State Association?—A. No.

Q. Do you agree with Dr. Pidolski?

Mr. DORAN. Will you state for the record the book you are reading and the page, so we can examine it later.

Mr. FLEISCHMAN. "Medicine Marches On," by Edward Pidolski, Harper's Magazine, Page 187.

The COURT. President of the New York State Medical Association; is he now the president?

Mr. FLEISCHMAN. Yes, as far as I know. I am quite sure he was elected within a month.

Q. Will you read this paragraph?

Mr. DORAN. Objected to as improper cross-examination.

Mr. FLEISCHMAN. Just reading it to himself.

Mr. DORAN. All right, pardon me.

(Witness reading article.)

Q. Have you read it?—A. Yes.

Q. Have you ever seen it before?—A. No.

Q. Do you agree now with Dr. Pidolski where he is saying that the frog method is never proper or accurate?—A. I don't agree.

Q. Do you know who Marvin R. Thompson is?—A. Yes.

Q. Who is he?—A. Director of the Warner Institute.

85 Q. What is the Warner Institute?—A. That is the commercial laboratory set up by a large commercial manufacturer in New York City.

Q. Is he on this committee that you are talking about that studies digitalis?—A. He is, yes; he is on that committee, I believe.

Q. May I read to you the other members on it?—Do you know Gruber; do you know him?—A. No.

Q. Clary?—A. No.

Q. Fenger, Geiter, Heil, Klein, and Nielson?—A. No.

Q. Then Cowles, do you know him?—A. No, I don't.

Q. Also Halliday, Swanson, Kirk Leed, Berrine, Beyers, and Raymond?—A. I know some of them.

Q. Look at the article, and particularly I want to, I want you to read it yourself; this is the article.—A. [Witness reads article.]

Q. Do you recognize that, Doctor, this paper which I have given you?—A. You mean this was officially published by a regular scientific journal?

Q. It was, this discussion of these men.—A. No, I don't know; I am not a member of that committee.

Q. Now, having read what you read, and assuming for our purpose it is authentic and it is the report of the committee on

pharmacological assays in May 1941, is that what they meant?—
A. I believe so.

Q. Keeping that in mind, I want to know if you agree with it; what was said?

Mr. DORAN. That is objected to.

Mr. FLEISCHMAN. All right, we will come to it in another way.

Q. Digitalis loses its potency, does it not?—A. Yes; I believe it does.

86 Q. Now, in the liquid, would it lose its potency within as much time and what percentage of potency would it lose?—A. Within a year, after 11 months, I would say it would lose about 50 per cent of its potency.

Q. 50 per cent, do you mean that? If I were to tell you 70 per cent, would you disagree with me?

Mr. DORAN. You are questioning on the liquid digitalis?

Mr. FLEISCHMAN. Yes.

Mr. DORAN. I ask to strike it out.

Mr. FLEISCHMAN. I have allowed this witness to roam all over the world.

The COURT. This man is the expert and he is really testing his qualifications, both direct and indirect, and I will receive it.

Q. What do you say?—A. I would say it deteriorates about 50 per cent.

Q. I would say about 70 percent from the words of the Government expert, and if they were to say so, would you disagree with that?—A. I would say from 50 to 70 per cent, it doesn't make much difference.

Q. It is 20 per cent difference?—A. Yes; but it is so deteriorated.

Q. Now, then, in what other forms do you put up the digitalis?—A. Put it up in tablets and the powder extract, and the tincture and in pills.

Q. You put it up as I get it now, in tablets; you put it up in what tinctures?—A. Powdered tincture.

Q. And in pills?—A. Yes.

Q. Take the first one, the tablets, do they lose their potency?—

A. Tablets are supposed to be generally very stable.

87 Q. But they do lose their potency over a period of time, don't they?—A. Over a period of time.

Q. What time, you are the expert, tell me about it?—A. Over a period of time, Parke-Davis ran experiments on powdered digitalis and kept it as long as five years.

Q. How about Upjohns?—A. They kept their pills about 18 months.

Q. And you say Parke-Davis kept it longer than that?—A. I didn't say that. I say they ran experiments on powdered digi-

tal, and they kept the powdered digitalis for five years, without it losing perhaps more than 20 per cent of its potency.

Q. Now, Doctor, the digitalis in the tablet form, what will cause it to lose its potency, exposure?—A. No one knows what.

Q. Assume that it is exposure. The exposure happens, does it not? If you left the bottle open the moisture would?—A. (No response.)

Q. Pardon me, do you understand me, I said moisture?—A. It might possibly.

Q. Well, I don't know. Does it or does it not?

Mr. DORAN. I object to the question. I submit that he should ask the question and not comment both on the question and the answer.

The COURT. I think you might get the answer if you break your questions up.

Q. Is that the reason?—A. Yes.

Q. Let me make it simple. Do you, as a matter of fact, tell us from your experience as an expert that moisture does have an effect on the potency of digitalis?—A. To tell you the truth, I never worked on deterioration of digitalis. I am not a fit witness on that as far as that is concerned.

88 Q. That is a perfect answer, but you know there are elements that cause deterioration and cause the deterioration of digitalis?—A. Must be.

Q. And the extent is more in the liquid than in the powder form?—A. Yes.

Q. Have I got your answer to the District Attorney correct, you say you assayed these samples in this case on May 4, 1940; is that correct?—A. No, I said March 4.

Q. That is right; March 4, 1940?—A. Yes.

Q. Now, sir, do you know Dr. Chapman?—A. Yes, I do.

Q. You will agree that he is an authority on digitalis?—A. Yes; he is considered an authority on that drug.

Q. He is considered a great authority on digitalis?—A. Yes.

Q. What university does he teach the subject in?—A. University of Maryland.

Q. And he works with the Government in a great many cases?—A. Yes.

Q. And is looked upon as a very excellent authority on digitalis?—A. Yes.

Q. Now, on March 4, 1940, you found digitalis in a sample, given to you, that it contained 42 per cent; is that correct?—A. That is right.

Q. Now, if I were to say to you on that same digitalis, that same digitalis that Dr. Chapman on June 4, 1940, found it O.K.

above the 80 per cent, between 80 and 120 per cent allowed by the Government, what would you say to that?

Mr. DORAN. I object to that. That is an indirect way of trying to establish whether some other expert made an analysis of these.

The COURT. I will have to sustain the objection, because it is based on an analysis not testified to. You are assuming something that has not been proved.

89 Q. Mr. FLEISCHMAN. When I make a statement of that character, I suppose you might think I will prove just that.

The COURT. We will not assume that at all.

Q. Is it possible, Doctor, for you to make an examination of digitalis on March 4, 1940, and find that 42 per cent potency and on the same material for another chemist to find an 80 per cent potency, and if so, why?

Mr. DORAN. I object, trying to assume in that question what has not been proven.

The COURT. Oh, no. I think as an expert, he might be able to say that two chemists can analyze the same object and obtain different results.

Q. Do you think it is possible?—A. Yes, I think so, but—

Q. But what?—A. That is all.

Q. You want to cut the "but" out and put a period there. Now, you say you cannot tell me the various elements, you won't admit the various elements that cause the loss of potency?—A. No.

Q. Do you or did you not know that the sample that you had had been examined by a representative of the State of New York at about the same time you examined it?—A. I didn't know that.

Q. Do you know it has been tested by Mr. Slade of New York?—A. Yes.

Q. What position does he occupy?—A. Well, I don't know him.

Q. Did you say that you were with the Upjohn Company?—A. I was.

Q. Doctor, do you know G. H. Sherman, M. D.?—A. Sherman is the name?

90 Q. G. H. Sherman, is the name?—A. Yes; I heard of the Sherman laboratory.

Q. A good laboratory?—A. Why, I—

Q. Do you know of Parke-Davis & Company?—A. I have heard of them.

Q. Will you read this communication by their chemist, Dr. Taylor, their chief chemist?—A. I have heard of him.

Q. Is he their chief chemist; do you know that?—A. Yes.

Q. Read that letter [Attorney handing letter to witness].—A. [Witness reading letter.]

Q. I want to know from you, Doctor, as a matter of fact if that isn't the thing that is disturbing the entire chemistry industry, as far as digitalis is concerned, that they don't know how to avoid the loss in potency of digitalis?

Mr. DORAN. I object to the question, on the ground it is an indirect way of getting into evidence some portion of the letter written by some unknown person.

Mr. FLEISCHMAN. You can read it.

Mr. DORAN. Yes; I want to read it. You cannot prove a letter that way, and I object to it.

Q. Have you had direct experience in chemistry with regard to digitalis?—A. Have I had direct experience with that? Only while I worked for Upjohn.

Q. Outside of that?—A. Well, I receive a lot of samples every month.

Q. With your single experience with Upjohn Company, who are very good chemists, aren't they?—A. Yes.

Q. Were you working on digitalis then?—A. I assayed digitalis; yes.

91 Q. Did you find that their great trouble was in finding out how to avoid the loss in potency of digitalis?—A. No.

Q. You didn't find that to be the case?—A. Not in that time; that was 1933 to 1936.

Q. The condition hasn't changed any?—A. We have another method of assaying it.

Q. You mean it wasn't as good as the other? There must be no trouble now, or you have gone backward, isn't that it?—A. The way it was done that time, wasn't as accurate as the way we are doing it now.

Q. Why?—A. The way we did it then was not as accurate as the way we do it now.

Mr. FLEISCHMAN. That is all.

Mr. DORAN. That is all.

The COURT. We will adjourn now until tomorrow at ten A. M. (Proceedings adjourned to July 1, 1941, at 10 A. M.)

Proceedings of July 1, 1941, at 10 A. M.

Present: Hon. HAROLD P. BURKE, District Court Judge. Appearances: Same as before noted.

HAROLD J. TAGETT, called as a witness on behalf of the Government, and sworn, testified as follows:

Direct examination by Mr. DORAN:

Q. Doctor Taggett, you are a practicing physician?—A. Yes, sir.

Q. Will you speak up, please?—A. Yes, sir.

Q. Where do you practice?—A. Rock Creek, Ohio.

Q. How long have you practiced medicine?—A. Eight years.

92 Q. You are a graduate of a medical school?—A. Ohio State University.

Q. And were admitted to practice medicine in the State of Ohio?—A. Yes.

Q. And have been engaged so for eight years in fact?—A. Yes.

Q. What is your practice, general?—A. General practice.

Q. Where do you maintain your office?—A. In my home.

Q. In your home?—A. Connected with my home.

Q. Just tell the jury what your office consists of—A. It just adjoining to the home, just the office and reception office; and a little drug room adjoining the office.

Mr. FLEISCHMAN. Just a little louder, please, Doctor.

Q. Tell us about the drug room.—A. Oh, it is really the drug room, a closet about five or six feet long, maybe three feet wide, and right adjoining the office.

Q. What do you keep there?—A. The drugs there; it is the drug room.

Q. Is there anyone else that has access to it at all, other than yourself?—A. No.

Q. There is no other physician, I take it that has his office there with you?—A. No; I am the only one in town.

Q. You have no others there?—A. No.

Q. Doctor, was there a time in January 1940, when you purchased a quantity of digitalis tablets from the Buffalo Pharmaceutical Company at Buffalo?—A. Yes, sir.

Mr. DORAN. Mark this for identification.

(Order marked "Government's Exhibit No. 6" for identification.)

Q. I show you Government's Exhibit No. 6 for identification, and I ask you to examine it and state whether that 93 is the order which you sent to the Buffalo Pharmaceutical Company for digitalis tablets?—A. Yes, it is.

Q. When did you send it?—A. January 8, 1940.

Q. And when did you receive delivery of the tablets?—A. Well, I don't know exactly, they are always fairly prompt in deliveries, should be within two or three days.

Q. Two or three days, all right. How many tablets did you order, Doctor; the digitalis tablets?—A. 1,000.

Q. What type tablet did you order?—A. 1½ grains, one U. S. P. unit.

Q. The order, this exhibit, did that accompany that shipment when you got it?—A. It came right back with the shipment.

Mr. DORAN. Any objection to it going in evidence?

Mr. FLEISCHMAN. No.

Mr. DORAN. I offer it in evidence.

The COURT. Received.

(Government's Exhibit No. 6 for identification received in evidence.)

Q. I show you Exhibit No. 3, in evidence, Government's Exhibit Number 3 in evidence, Doctor, and I ask you to examine it, and state whether or not that is the bottle, or a portion of the digitalis tablets that you received in that shipment that you just mentioned in your testimony?—A. Yes, it is.

Q. When you received that bottle by shipment from the Buffalo Pharmacal Company of Buffalo, Doctor, tell the Court and jury if you will, in what condition it was?—A. Well, the bottle was sealed. It has a screw top.

Mr. FLEISCHMAN. A little louder, please, Doctor.—A. The bottle was sealed with a screw top and around that was a cellophane wrapping, I guess it was also sealed around it.

94 Q. Where did you keep that bottle, Doctor, from the time that you received delivery on it until—A. Right in what I call the drug room, adjoining the office.

Q. Did you keep it capped all the time?—A. Always.

Q. There came a time, did there not, I believe it was the latter part of February, when one of the inspectors, that you know by the name of Mr. Faries, picked up or purchased that sample?—A. That is right.

Q. That was the latter part of February 1940, was it not?—A. February.

Q. Had you used some of these tablets in the meantime?—A. I believe I used approximately half of the bottle.

Q. So there were about 500 left in the bottle?—A. Yes.

Q. Did you add anything to the bottle in any way?—A. Nothing at all.

Q. Nothing had happened to it, except this, that you used approximately half of the tablets in the care of your practice?—A. That is right.

Q. Are the conditions in that drug room of yours normal as they would exist in the ordinary home?—A. Yes.

Mr. FLEISCHMAN. I object to it on the ground it calls for a conclusion.

The COURT. Have him describe it.

Q. Well, is there anything unusual about the conditions in that room?—A. The office is the same as the living room quarters. I keep it a uniform temperature, it is part of the office, and the office is kept at a uniform temperature like I do the living quarters.

Q. Doctor, when you received the delivery of this bottle, of digitalis tablets from the Buffalo Pharmacal Company, what strength digitalis did you assume you were getting?—A. One and one-half grains, one U. S. P.

95 Q. And you relied upon that representation upon the label, did you?—A. Yes, sir.

Q. Doctor, you are a practicing physician of eight years experience. Tell the Court and jury what digitalis is used for in the practice of medicine.

Mr. FLEISCHMAN. Of course, that is objectionable, it seems to me. I don't know the purpose of it, nothing to do with this litigation unless you want it. It is only for the purpose of creating an atmosphere of alarm.

Mr. DORAN. I will state my purpose.

The COURT. It doesn't make any difference what they were intended for, the statute was made regardless of what they were to be used for.

Mr. DORAN. I take it that is so, except that I assume I have the right to show the reason from the medical standpoint of the importance of the full strength of digitalis.

The COURT. That makes no difference. Congress prescribed certain tests and whether reasonable or not, that is the law.

Mr. DORAN. That is true. May we be permitted to show the reason back of that, the importance of that?

The COURT. I don't think it is proper; that might create a prejudice in the minds of the jury.

Mr. FLEISCHMAN. I think in view of this suggestion I want to withdraw the objection; I want the jury to know all about it.

The COURT. All right.

Q. Do you recall the question?—A. Yes, sir. Where the digitalis is used, it is the action of the digitalis, it acts 96 directly upon the heart muscles, increasing the strength of each contraction of the heart; it is a cardiac stimulant, and also used in weakened hearts to increase strength of its action.

Q. Is it used in the field of medicine solely in the treatment of heart ailments, or are there other things?—A. Heart ailments.

Q. Ordinarily, how do you use it, how do you administer or prescribe it?—A. Well, it depends on the case. If you have a heart condition where you want a repeated dosage, that dosage would depend on the body weight, you would give one U. S. P. unit for each ten pounds of body weight.

Q. It is the practice of you in the treatment of heart ailments in prescribing of or administering digitalis, to figure out the dosage of the particular person and as the circumstances may require?—A. Yes, it is; it has to be accurate.

Q. Is it very important for you as the physician, to know the strength of the digitalis you are prescribing?—A. That is right.

Mr. DORAN. You may ask.

Cross-examination by Mr. FLEISCHMAN:

Q. Doctor, it is important to every physician to know what he is prescribing?—A. That is so.

Q. And that applies not only to digitalis, but to anything in your work?—A. Yes.

Q. Even with castor oil, that you don't give too much of it?—A. Yes.

Q. Doctor, now the 1,000 pills that we are talking about, or tablets, those that you bought, they cost 80 cents. It is a cheap commodity; 80 cents for 1,000?—A. I don't recall what it was.

97 Q. Approximately.

Mr. DORAN. I think it was \$1.60.

Mr. FLEISCHMAN. That is right.

Q. \$1.60 for the whole thousand.—A. Yes.

Q. You would call that kind of a cheap drug, isn't it? It is commonly used?—A. Yes; it is commonly used.

Q. And is a prescription required for me to get those in a drug store?—A. Yes.

Q. But the drug store keeps it; any drug store keeps it?—A. Yes.

Q. And that is the price, the usual price as you bought it before, isn't it?—A. Yes; I have bought it before.

Q. Now, sir, questions were asked of you with regard to the Buffalo Pharmacal Company. That is a high-class concern, isn't it?

Mr. DORAN. I object to that.

Mr. FLEISCHMAN. I have allowed everything here.

The COURT. Yes, but you withdrew your objection.

Mr. DORAN. I said nothing about the reputation or good faith of this company. It is an entirely different question.

The COURT. Do you want to know about the good faith of the Buffalo Pharmacal Company?

Mr. DORAN. I make no claim of that.

Mr. FLEISCHMAN. I started out to say that we will prove that we use the very best stuff and—

The COURT. I see no need for this argument. It makes no difference. If you have some other argument I will be glad to listen to it. In view of the statute no matter what the intentions were, no matter how good their reputation was, it is immaterial. The statute makes it as it is.

98 **Mr. FLEISCHMAN.** As we stand here we have an individual defendant here, and I think I have the right to prove the good faith as we stand now.

The COURT. I cannot follow your argument, and I cannot see the difference between the individual and the corporate business.

Mr. FLEISCHMAN. We will assume that our office boy sent out some stuff and from a responsible concern, he takes it off the shelf and sells it, he has every reason and right to suppose it came from a very reliable concern, perhaps the most responsible in the country, and he sends it out, and your contention as I get it now—

The COURT. I think I would be glad to rule that the office boy would be equally guilty.

Mr. FLEISCHMAN. That is a proposition on which you are now ruling?

The COURT. Yes.

Mr. FLEISCHMAN. I will respectfully take an exception.

Q. How long have you used digitalis?—**A.** Well, ever since I have been in practice, eight years.

Q. How long have you dealt with the Buffalo Pharmacal Company?—**A.** I don't recall. I would say three or four years.

Q. That is as long as they have been in existence, I take it for granted?—**A.** Three or four years.

Q. That as I say is how long Mr. Dotterweich created this company and been working there. Have you at any time in your experience in the purchase of digitalis from the Buffalo Pharmacal Company ever had any bad results or any objection from any source as to the potency of the drug which they supplied you with?—**A.** Just once. I recall about a year ago,

99 **I observed** some nauseating and vomiting in the ordinary dosages I had been giving. Some of the patients were being nauseated and vomiting and since that time, you have it in your record, I understand over the red-coated rather than the uncoated tablets.

Q. The question of nausea was because of the overdosage, not in the usual dosage?—**A.** Well—

Q. That is the fact, isn't it?—**A.** That is the first thing you think of, you think it would be that although I didn't increase the dosage.

Q. In other words, if you, supposing you were giving a patient a tablet of $1\frac{1}{2}$ grains, digitalis, and as matter of fact it was less than $1\frac{1}{2}$ grains, that wouldn't create the nausea, would it?—**A.** No; it wouldn't.

Q. And if you supposed you were giving $1\frac{1}{2}$ grains, and actually giving three that would create nausea?—**A.** Oh, yes.

Q. So the contention here raised by the Government that the pill would be an underdosage, less than $1\frac{1}{2}$ grains, that doesn't create anything for which anyone could be blamed, the condition you are talking about, the nausea in the one case in mind, that we talked about?—A. No.

Q. Then, Doctor, may I ask you this: I take it, if you used within two months that you had this bottle, if you used 500 or half of it, you have quite a practice over there in which you use digitalis?—A. Just a moderate practice of medicine.

Q. That is quite a good business if you use 500 tablets over a period of two months or less that you had the drug in your custody.—A. You mean it is a large amount to you?

Q. No; I mean it shows you have a great many patients that use it?—A. Yes.

100. Q. I am not finding fault with you or anyone else here, but that is correct, Doctor? In all cases that you prescribed for patients, you never had any trouble with regard to digitalis furnished you by this company?

Mr. DORAN. I object to that.

The COURT. I will sustain the objection.

Mr. FLEISCHMAN. I respectfully take an exception.

Q. Now, have you bought any other drugs from the Buffalo Pharmacal Company?—A. Oh, yes.

Q. And you are still buying from them?—A. Yes, sir.

Q. Now, in using 500 tablets of digitalis over a period of two months, and assuming that you have occasion to open that bottle right along and close it up the same as any other doctor does?—A. Yes.

Q. And I assume, being a busy man, it is very possible that you leave the bottle open for awhile, do you not, like anybody else?—A. To take the tablets out.

Q. But if you are called away for any period, that bottle would be open?—A. Oh, no; I always keep the bottles well stoppered.

Q. Well, would all of them be so well stoppered?—A. Yes, sir.

Q. In the way it ought to come, as you know it ought to come, to be stoppered, is that it, for digitalis?—A. That is right.

Q. Because you think digitalis loses its potency?—A. What form of digitalis?

Q. The digitalis that you had there in the drug room; it loses its potency right along?

Mr. DORAN. I submit this is improper.

The COURT. Proceed. Objection overruled.

191. Q. You know, do you know as a physician in active practice for sometime and having all the business that you have indicated here and dealing with digitalis that digitalis in any form loses its potency?

Mr. DORAN. Objected to, because digitalis is in the tablet form here.

The COURT. He asked if it loses its strength in any form.

Q. Is that correct?—A. I don't think they lose their strength if you keep the bottle properly stopped up, using a cap, keeping the moisture away. I don't think that the tablets of digitalis will lose any potency; not the tablets.

Q. That is based upon your experience?—A. Yes; it is.

Q. And the best test of the potency of the digitalis, Doctor, from your experience, as I get it, is upon the human being rather than cats and frogs or any other animal?

Mr. DORAN. I object to that, as it describes the method of testing. It is immaterial I submit. Under the statute there was no other test permissible, that is the one that Congress said must be followed wherever the test is laid down in the United States Pharmacopeia.

The COURT. The U. S. Pharmacopeia doesn't lay out this frog test, does it?

Mr. DORAN. That is the only one.

Mr. FLEISHMAN. It hasn't been offered in evidence yet.

Mr. DORAN. I can offer it right now. Congress makes it mandatory as to what test must be followed.

The COURT. We went into this question at length yesterday about the different kinds of tests. What is the question now? Well, reframe your question.

102 Q. Doctor, the best form of test of digitalis is upon a human being, isn't it?—A. While I would know the action of digitalis on a human being, I don't know the action on any other animal.

Q. Therefore, we will take the human animal for our purpose here, and you have the test of the human being.—A. Yes.

Q. And a slighter action we will get?—A. With the one exception.

Q. That is in some there is a nauseating effect, in how many cases that you have had?—A. Well, several of them had the same kind, that is when I changed to the coated tablet.

Q. What I am trying to say is, except in the instance of the nausea which we get, do we not, or don't we agree that it comes from using too much digitalis, rather than too little? You cannot blame the digitalis for that, if it is in a less form than you prescribed?—A. That is true, but the reason I changed primarily was, I also had the dosage the same in subsequent bottles of un-coated tablets. I keep the dosage the same in the patient.

Q. Let us stick to Exhibit Number 6, the thousand tablets that you purchased from this company on this occasion, were there

any ill effects produced or exactly the result you wanted in the patient you treated?

Mr. DORAN. I submit that is the same question asked.

The COURT. I will receive it.

Q. Do you remember the question before?—A. What effect that I had with this particular bottle?

Q. Yes; the 500 in the bottle to which you switched over.—A. I didn't notice any particularly bad effects.

103 Q. What I mean is, it produced the effect that you expected it to produce on the human being for whom you were prescribing, that is correct, isn't it?—A. In a way, yes. I would say it had no bad effect, that particular bottle.

Mr. FLEISCHMAN. That is all.

Redirect examination by Mr. DORAN:

Q. The nausea is the indication of poisonous effect?—A. Digitalis poisoning, sometimes referred to as digitalis poisoning.

Q. And digitalis is a poison?—A. Yes; in overdoses.

Q. And this could very well happen, that you could be without knowledge on your part, prescribing out of a bottle, a digitalis bottle that you assumed the tablets were of full strength as labeled. Now, assuming they were half strength, that same patient might at a drug store or at some other place, purchase the same type of digitalis tablets and you would have some pretty serious results?—A. That is right.

Mr. FLEISCHMAN. I object to what might happen in another case. We are dealing with this case.

The COURT. I think we are going pretty far afield here.

Mr. FLEISCHMAN. I will withdraw my objection.

The COURT. What I understand, that is what would happen if they got other tablets in the drugstore.

Mr. DORAN. Of full strength, and if they had been using the dosage that the doctor prescribed.

The COURT. Sustained. It is too speculative.

Mr. DORAN. That is all.

Recross-examination by Mr. FLEISCHMAN:

Q. My associate wishes me to ask you this question: When you take the tablets of digitalis in your hands, there 104 is necessarily a moisture on that tablet, isn't there?—A. If you put it in your hands.

Q. And you know that moisture has a very deteriorating effect on digitalis?—A. Moisture does; yes.

Q. Do you happen to know what moisture there is in the digitalis tablets?—A. No; I don't.

Q. Now, coming back to the last question asked you by the District Attorney, is it or is it not a fact that this nausea follows

from having too much digitalis rather than too little; isn't that so?—A. This trouble usually the first time is from too much digitalis.

Q. That must be evident. If it had no strength at all it would have no effect at all, that is, the general effect?—A. Yes.

Q. And if too much strength it will hurt?—A. Yes.

Q. And if too little, it cannot hurt you?—A. That is right.

Mr. FLEISCHMAN. That is all.

Mr. DORAN. Of course, it is "equally true that you don't get the result that you desire with the half-strength tablets."

The WITNESS. No; naturally.

Mr. FLEISCHMAN. But you don't get the result that you want, that is what you told us.

The WITNESS. No; I don't get the result, that is why I increased the dosage of the tablets.

Mr. FLEISCHMAN. But then you did get the result when you found what you wanted?

The WITNESS. I really didn't have any left of the tablets after the inspector took them. I ordered more.

Mr. FLEISCHMAN. And who did you order more from?

105 The WITNESS. From the Buffalo Pharmacal Company, and that is when I got the nausea and the vomiting.

Mr. FLEISCHMAN. That is all.

Mr. DORAN. That is all.

HERBERT A. BRAUN, recalled, testified further as follows:

Mr. DORAN. Will you mark this for identification, please?

(Chart marked "Government's Exhibit Number 7" for identification.)

Redirect examination by Mr. DORAN:

Q. Dr. Braun, in making the test that you testified about, yesterday, of this digitalis, did you obtain certain results?—A. Yes; I did.

Q. And how were those results computed, Doctor, that is, I mean in figures?

Mr. FLEISCHMAN. May I add at this point, that is the question raised awhile ago. If he goes into the question of tests, I want to know what tests he made.

Mr. DORAN. You could have cross-examined him yesterday.

Mr. FLEISCHMAN. Well, you objected—

Mr. DORAN. No, I don't. My only point, your Honor, is that the next witness who also made an analysis or a test of this digitalis, has made a chart on which he intends to use as a part of his testimony, and in the chart in addition to his figures, are certain figures obtained on the result by Dr. Braun.

The COURT. What is the question now?

106 Q. Were there any results in figures in the test you made on that chart?—A. Yes; the figure in my case is March 12th.

Mr. FLEISCHMAN. Was this test made upon this bottle?

Q. Were they the result of the test of this sample in question?—A. Yes.

Q. Do they correctly show under those dates the result and the figures that you obtained?—A. Yes; they do.

Q. And you, I take it, had something to do with Dr. Miller in the preparation of this chart?—A. That is right.

Q. So that it contains your result and figures as well as his?—A. That is true.

Q. And those that are yours are under date of March 8th to 11th?—A. The 8th to the 12th.

Mr. DORAN. That is all.

Recross-examination by Mr. FLEISCHMAN:

Q. Dr. Braun, I ask you this: Do you want to tell this jury that someone else worked on the test with you?—A. I did the test alone, but there were two analyses.

Q. Let me put it this way: Are there any two men in your experience, you and anyone else that can make the test and have the same result on the digitalis?—A. Yes—not exactly the same.

Q. Why not?—A. Without—

Q. Did you hear my question?

Mr. DORAN. Let him answer the question, please.

Mr. FLEISCHMAN. I don't think he got the question. I will ask the same question, but try to make it understandable to him. I hope.

Q. Dr. Braun, when I asked you—what I asked is, is it the fact there are no two men, no matter how well trained that will get the same result in tests upon the same digitalis?—A. They do get the same results within limits, I mean.

107 Q. Then they don't get the same results. I want to know why they don't get the same results if your test is accurate; why do you not get the same results; two plus two makes four?

Mr. DORAN. There are about four questions in that one.

The COURT. I think the doctor understands the question. I think if you will ask him to explain, that he can explain.

A. Well, that is true, we have a group of people, all of these people with the same drug, won't react the same way, and that is the way in tests of animals too, but if you take the average of the proper type of animal or a large group of people, the average result will give you the result that you desire or want.

Q. Well, it is not an exact science, is it?—A. It isn't as exact as physics or mathematics; it is biological.

Q. And therefore, we get away from two and two making four?—A. We have living subjects.

Q. Supposing I take this bottle of tablets and you were examining it and all the other experts of the Government here would examine it, would you reach the same conclusion?—A. Yes.

Q. Are you sure; precisely the same?—A. Not precisely.

Q. Why not; if the same bottle and you are applying the same test, not on a living animal, but on chemicals, why not?—A. Because you are working with living things—

Q. Doctor—

Mr. DORAN. Please let the witness answer, Mr. Fleischman.

Q. Doctor, I am talking about the tablets, if each one of the Government experts here could now test the contents 108 of this bottle, not on living things, will you reach the same conclusion as to its make-up?—A. As close as we could expect to come on living things, working on living objects, living test objects.

Q. What living test objects are you talking about?—A. Upon the frog.

The COURT. Well, you know what he means.

Mr. FLEISCHMAN. I will give you my assurance I did not.

Q. Perhaps you can make it plainer.

The COURT. Yes; I can. He pointed out that he makes the test on frogs, that is perfectly clear, we understand that now.

Mr. FLEISCHMAN. I don't understand that. I am sorry.

Q. You mean if you took this pill here now, you couldn't make any test at all?—A. No; unless I test on a living animal.

Q. Some of the frogs are different and when you give these tablets for testing purposes, you get a different result?—A. If we take enough frogs, we would get the same result; I could duplicate the result perhaps 19 out of 20 times.

Q. Exactly?—A. Within a certain range.

Q. What is the range, that is what I am trying to get at.—A. Within ten per cent.

Q. Within ten per cent?—A. Within ten per cent.

Mr. FLEISCHMAN. That is all.

Mr. DORAN. That is all.

109 LLOYD C. MILLER, called as a witness on behalf of the Government, and sworn, testified as follows:

Direct examination by Mr. DORAN:

Q. Dr. Miller, are you connected with the Food & Drug Administration?—A. Yes; I have been, five years today.

Q. In what capacity?—A. As senior pharmacologist.

Q. Tell us what a senior pharmacologist is.—A. The pharmacologist is generally an individual who is concerned with the action of drugs on living things, including humans and animals, and in that connection the Department of Agriculture, and now the Federal Security Agents, depend upon the pharmacologists to carry out the biological tests on living things.

Q. And that is what you do?—A. Yes; that is my work.

Q. Tell us, Doctor, the education you have had.—A. I obtained a B. A. from Pōnoma College and a Ph. D. from the University of Rochester here in this city in 1933.

Q. Did you specialize or major in it?—A. Yes; I specialized in biochemistry and pharmacology here at the University.

Q. And you received a degree from the University here in Rochester?—A. Yes.

Q. Majoring in biological chemistry, is that it?—A. Yes; a pharmacologist. I was interested in pharmacology and I taught pharmacology here in the school of Medicine, here, at the University.

Q. While you were taking the course, Doctor?—A. Yes.

Q. And after you received your degree and graduated from the University of Rochester, did you then go with the 110 Food & Drug Administration?—A. No. I was awarded a research fellowship with the Upjohn Company and spent two years in research there in drugs.

Q. What sort of fellowship was that, by the way?—A. It was a competitive fellowship open to all who wished to apply and I believe some ten or twelve of these fellowships were awarded from 600 to 800 applicants, I understand.

Q. They dealt with what, these fellowships?—A. I was working on formulae, which are biologically active drugs, and we were preparing it, and testing it on the animals in the course of our research. It has since developed to be a very important drug in connection with pregnancy.

Q. And then you, I take it, were engaged in that work for some two years after you left the University of Rochester?—A. Yes.

Q. Are you a member of any society or committee in your field?—A. Yes; I am a member of a number of them, the most important of which is the Society for Experimenting in Biology and Therapeutics, in which the membership is by invitation from the body itself, which is considered somewhat of an honor. I am a member of a number of associations and joined by simply paying the dues, and qualifying by virtue of the profession.

Q. Have you received any honors of any sort in your field?—A. Yes; I was fortunate enough to receive the Ebert prize last year, which I was given to understand, was to be considered the highest honor that can be awarded anyone in the profession of

pharmacy, and given by the American Pharmaceutical Association, given annually for the most meritorious paper presented during the year.

111 Q. On what subject was the paper?—A. On the assay of digitalis.

Q. And when you use the term or word "assay," you mean testing to the layman?—A. Yes; I mean a test.

Q. Now, I take it that pretty well covers the field of your education and your experience up to the time you went with the Food & Drug Administration?—A. Yes.

Q. Since you have been with the Food & Drug Administration, you have been engaged in the type of work you mentioned generally; tell us what particular drug or drugs you have worked on actively.—A. I originally went to the Department to assay ergot and pituitrin, both drugs concerned with process of childbirth. In that connection—

Q. I don't care so much about the details of that. You have done a great deal of work in the assaying, the testing of digitalis?—A. Yes; for at least 18 months I worked almost exclusively on it, and I had been in the fortunate position that I have been a member of a committee which is working under the auspices of the United States Pharmacopeia, the revision committee, the said committee concerned with keeping that book up-to-date. I have been working with the committee, studying this particular method of test for digitalis.

Q. Now, do I understand you correct then that for the past 18 months, your work as pharmacologist for the Administration has been confined solely to the testing of digitalis?—A. Concerned with the testing—part of my duties is to check Dr. Braun, when he finds a bad sample, we always want to have two independent tests made, so that immediately when he finds a bad sample, he turns the sample over to me, and I run an independent 112 test. That is part of my work. Another part is to carry on a check as to the accuracy of the method, to see if by any means we can improve it.

Q. I take it then from your answer that you have undoubtedly assayed a great many samples of digitalis.—A. Oh, yes.

Q. Have you any approximate idea of the number?—A. Well, in the course of my research and the routine tests when Dr. Braun is away on the other matters, I assayed in the neighborhood of 200 or 300 samples.

Q. Now, to begin with, tell us what digitalis is.—A. Digitalis is a plant in its nature. As Dr. Braun said, it grows commonly in gardens, and is a very beautiful flower. The leaves contain that which is valuable, and as Dr. Tagett said, in the treatment of heart disease and for that reason the plant is cultivated. The

leaves when the plant reaches maturity, are carefully dried under conditions prescribed in the Pharmacopeia, so that the activity will not be destroyed, and then they are ground up in powder and used in medicine.

Q. Just for our information I assume what has been said here before, but I would like to have you tell us about it, the digitalis is made up and put out in different forms, that is, the liquid or tincture and tablets and so on.—A. Yes. This leaf is put up in various forms. As you say it is in the liquid form, known as tincture, put up in capsules, if it is in the little gelatine capsules and dispensed. It is put up in tablets, the dry form, pressed into the tablets. Now, the actual amount of the active principal, the amount that does the patient some good, that cannot be determined by a chemical means.

Q. As I understand it, from what you just said, there 113 is no method of a chemical analysis of the digitalis?—

A. No, you cannot. The same leaves as it comes, some leaves may be grown under particularly favorable conditions, so the amount of the active principal in that leaf might be twice as much as the leaves grown in another part of the country under different conditions.

Q. And that is true of the tablets then?—A. Yes.

Q. Therefore, you feel you must rely upon a biological assay or with animals?—A. Yes. We observe the effect on the animals and that is the only means we have to determine the activity.

Q. Doctor, you of course are familiar with the U. S. Pharmacopeia?—A. Yes.

Q. There was some testimony about it yesterday by Mr. Berman as to what it is and how it has been published and how often it comes out and so, is that correct, do you agree with him as far as he explained it?—A. Yes.

Q. And that the United States Pharmacopeia is one of the official compendiums mentioned in the Food & Drug Act, which must be followed by you in the course of your work in making tests or assays? Is that right?—A. Yes, we have to follow it. It is prescribed by the Act, under which we work, and we cannot pick any other method, that we might think was almost as good or might be easier. We have to follow that one.

Q. And is it a fact, Doctor, that on page 397 of the 11th Revision of the United States Pharmacopeia there is a test or method there stated and provided for on the assay of digitalis?—A. Yes; this describes the way and the uses of frogs to obtain the strength. This particular section refers to the liquid form

114 because it is necessary in the course of making this test to put tablets such as that in the liquid form just immediately prior to their use. One cannot inject the solid tab-

let, you have to have it in the liquid form. In order to prevent duplications in making this book any larger than it is, the revision on page 36 that refers specifically to powdered digitalis such as that is, and tells how to put into the liquid form, so that this test on page 397 can be applied.

Mr. DORAN. As long as there has been some question raised about it, I would like to offer that page of the U. S. Pharmacopeia with respect to the test for digitalis which is found on pages 397 and 398, of the 11th Revision of the U. S. Pharmacopeia.

Mr. FLEISCHMAN. No objection.

(Pages 397 and 398 of the U. S. Pharmacopeia received as Government's Exhibit No. 8 in evidence.)

Mr. DORAN. Is there any other part of the U. S. Pharmacopeia that pertains to the test, for the actual test for digitalis?

A. Yes.

Q. If there is I would like to supplement my offer by that part of it.—A. On page 137, the standards of strength on powdered digitalis.

Q. And that is the provision under the heading "Powdered digitalis"?—A. Yes.

Q. On page 137?—A. Page 137; yes.

Mr. DORAN. I offer that in evidence.

Mr. FLEISCHMAN. No objection.

The COURT. Received.

(Page 137 of the U. S. Pharmacopeia marked Government's Exhibit Number 9 in evidence.)

Q. While we are on this subject, Doctor, is there a standard of potency for digitalis set up for the U. S. Pharmacopeia?—A. Do you mean the level of strength to which it must come?

Q. Yes.—A. Yes; that is outlined on page 137.

Q. So that is in evidence then?—A. Yes.

Q. Now, Doctor, I show you Government's Exhibit 3 in evidence and ask you if you have seen that exhibit before?—A. Yes; I recognize my handwriting on the seal.

Q. When did you first see it, by the way?—A. I saw this sample, as I recall it, about March 9, 1940.

Q. Where was it?—A. In my laboratory, in the Food and Drug Administration.

Q. In what condition was it when you saw it?—A. Essentially in the same condition as now, there were more tablets, and the cap was on tightly. The seal was broken and handed directly to me by Dr. Braun. It was not necessary in breaking the seal to give to me personally, if kept personally until I returned to him.

Q. Now, did you make a test or an assay of a portion of the contents of that exhibit?—A. Yes.

Q. And when was that made?—A. That was made, the preparations for it were begun on March 9, when I first received the sample, and it was completed on March 11th.

Q. For what purpose?—A. To find out whether the tablets in the bottle met the labeled claim, that is, whether each tablet had a potency of 1 U. S. P. unit.

Q. The potency there I take it, means the strength?—A. The strength, 1 U. S. P. unit.

Q. So that you made the test for the purpose of determining the strength to compare with that as labeled, and whether it would be 1 U. S. P. unit?—A. Yes; that is the purpose.

Q. Did you use a part of the tablets in that exhibit to make the test, Doctor?—A. Yes.

116 Q. How many?—A. I took thirty.

Q. And you made your test when, I think you told me, when you started?—A. I took thirty tablets from the bottle on March 9th and put them in liquid, which is specified in the Pharmacopeia, in order to get the drug into a liquid form, and that requires twenty-four hours.

Q. In making this test or assay which you just stated, do you follow the correct official test as laid down in the U. S. Pharmacopeia?—A. Yes.

Q. And the frog test is practiced?—A. Yes; that is the only test.

Q. Tell us in your own language, so we can understand, what you did.—A. As I said in the preparation for the test it is necessary to make the tablets in the liquid form, because the whole object of the test is simply to use the frog as the means of finding out whether these tablets are about as strong as required by the Pharmacopeia.

Q. Now, the Pharmacopeia provides, the outlined test of the Pharmacopeia provides that we use the powdered digitalis, which is the standard, so it is available to us, and all the other drug manufacturers.—A. As I said, the object of the test is to find out whether this material or any material one is engaged in testing, is equal to the strength required by the Pharmacopeia, so that this preparation is put into liquid form and the standard which we are supplied with is put in a liquid form. Now, these liquids must be used immediately within the course of one month in order that one may be sure he has exactly what he thinks he had and they must be injected just under the skin of the frog. Now, the Pharmacopeia provides they shall be diluted with water and the preparation contains about 70 percent alcohol, which would

117 interfere if injected full strength. Then the object is to inject the material on the one hand, and the sample on the other hand, the standard one, one type in the frog and another in a frog, both as near alike as we can get them. One hour after this frog has the injection, the frogs are anesthetized and their hearts are examined. The drug, the principal of this digitalis, it affects the heart of the frog in this way: First, it stimulates and causes it to beat faster and when it gets too much, it will cause the heart to stop, or when they get sufficient. So, at the end of the hour, the heart of these frogs are examined, and the object is to find out how much of the liquid which represents the sample, in this case, your given amount of liquid prepared from this standard powder. Now, we tell as to how much by trying to get the same approximately, approximately the same number of stopped hearts. That is to say, we will inject 20 frogs with a single dose of the preparation and if the standard stops the heart of ten of these frogs, and you give enough to stop ten of them, then we would definitely find out how much of this preparation would be required to stop approximately ten hearts.

Q. To interrupt you a moment, in explaining the test frame your words to actually state what you actually do in making this Pharmacopeia standard test.

Mr. FLEISCHMAN. Then I want to object, there is no proof what is standard, or who accepted it, or what it contains. If it is by application to another test which is called Standard, we have no proof of that. The District Attorney suggests something to him at this point, and I object.

The COURT. Describe the source. The objection is overruled.

118 Mr. FLEISCHMAN. You are taking it upon the theory that it will be subsequently connected with what the standard is. I don't know what it is.

The COURT. He told us where he procured it.

Mr. FLEISCHMAN. Still it must be proved that the standard was properly maintained and—

The COURT. The objection is overruled.

Q. Go ahead and complete your answer, but frame your answer to tell us what you did in this case.—A. Well, as I said before, I took thirty tablets, and made them into the liquid which should be equal to the amount on this label, and the amount of the liquid that I got from the standard. And if that were the case, then I injected a given dose, seeing that this dose was $3/1000$ of c.c. per grain into the frog. Might I use the blackboard here?

The COURT. It is up to the Counsel.

Q. Could you explain it more simply so that we understand it better by the use of this chart?—A. Yes.

Q. Did you prepare this chart in accordance with the results that you obtained in making the test in this case, Doctor?

A. Yes.

Mr. DORAN. All right. I offer the chart in evidence.

Mr. FLEISCHMAN. No objection.

The COURT. Received:

(Chart marked "Government's Exhibit Number 7" in evidence.)

Q. Where would you like to have it?—A. Where they can see it.

Mr. DORAN. We can put it on the blackboard.

The COURT. Put it on the desk here.

A. These results as indicated here, and which I am 119 prepared to testify were those obtained on March 11th, but I heard Dr. Braun testify on those obtained on March 8th to the 12th, but as I said, the object is to find out the dose of this material, this sample 78,786-D which the inspector puts on it when he picks it up, to find out how much of this material is equal to this. Then as Dr. Braun stated, the result is obtained—and it is assumed it is of the full strength—he injected ten frogs with a dose of 0.003, that is 0.003 of a gram, and the injection is according to the body-weight of the frog. He injected ten frogs and four had a stopped heart. He injected ten with the same strength and none. Then he injected 15 frogs with a higher dose and in those 15, 9 had stopped hearts, and when he injected an equivalent dose of this preparation, he only got two out of ten. When he injected the third dose which was still higher, than anything used in the standard, only five out of the ten frogs injected showed this typical stopped heart which was unsurvivable.

Now, in my test on March 11th, I used three doses of this standard preparation. With the said dose which is 0.003 c.c. of a gram, there were two stopped hearts out of 15, and with the 0.004 c.c. test, five stopped hearts out of 10. It is very easy to tell the difference between the 0.003 and the 0.004. The higher dose of 55/10,000 gave us a much greater effect, in 14 out of 15 frogs injected, so it is possible to distinguish the difference, double or less than double. Anyone can tell the difference between two and fourteen, and by the same token it is possible to tell whether the preparation is only one-half or full strength. The evidence that this preparation is only half strength is here: I had to go

up to a double dose, to use twice as much of this sample to 120 give the effect. I got the dose of 0.0055. c.c. and six out of the fifteen were stopped. With the intermediate dose of 0.008 c.c., only four out of the ten, just half as much as with the standard, where I got five out of ten. With a higher dose which is twice the one dose which I used for the standard 0.001 which

is 1/1000, I got that, a little bit less, which would indicate, taking these results on the whole, that the product was substantially one-half strength, and my conclusion was that this product was not greater than 48 per cent of the labeled strength that Dr. Braun testified to yesterday.

Mr. FLEISCHMAN. I object to what he testified to.

The WITNESS. I heard him testify.

Mr. DORAN. Just a moment. I think he wants to talk; I think Dr. Braun said 42 percent and this witness said 48 percent. I would like to have that.

The COURT. All right.

The WITNESS. These are the figures that led to the conclusion it was 42 per cent, which is substantially the same as this 48 per cent, and no question that it did not meet the labeled claim. I don't believe it is necessary to go any further. I believe it is clear.

Mr. FLEISCHMAN. May we have the doctor stop lecturing and tell so it is clear to us?

The COURT. That is the way any expert testifies. This is opinion testimony, and the jury will understand it is merely the opinion of the expert.

The WITNESS. These figures standing there in fact, indicate that this material, Sample 78,786-D has the strength of only one-half the standard of the Pharmacopeia, which gives the standard which should be met, and should be equal to it. 121 Therefore, this sample 78,786-D was only half the standard strength as given in the Pharmacopeia.

Q. Now, Doctor, so we will know, is there any material difference in the percentage of 42 and 48 per cent which you reached?—A. Not material for this reason: If the Court please, in assaying products, it is more difficult, because you have to give just so much. These are large doses for a frog. The 42 and 48 per cent, that is substantially the same result.

The COURT. May I ask a question: I understand there is a certain standard prescribed. Is there any margin of error allowed by the U. S. Pharmacopeia?

The WITNESS. Yes; there is a margin of error just to provide for this thing, that is, the small difference between one analysis and another. A wide margin is allowed, that is, 20 per cent below and 20 per cent above. Anything below that limit, 20 per cent, is too weak.

The COURT. So there is a range of 20 per cent above and 20 per cent below?

The WITNESS. Yes.

The COURT. And this you found was 48 per cent?

The WITNESS. Yes, way below.

Q. Doctor, what happened to it, in what condition was the balance of the sample kept after your test?—A. Kept tightly closed.

Q. And sealed?—A. Yes. I returned it to Dr. Braun, after my test; I returned it to Dr. Braun who sealed it.

Q. Where was it kept?—A. In our icebox, locked up.

Q. At the Food & Drug Administration?—A. Yes; we have a box, with a lock on the door, and Dr. Braun and I are the only ones having a key to that icebox.

122 Q. Now, was there a time, did there come a time, Doctor, when you sent out to someone else a portion of that sample, Government's Exhibit Number 3?—A. Yes; in the regular course of my work, a request, a letter from I believe a Mr. Whissel, was turned over to me requesting a sample, some tablets from this bottle. I believed they wanted two identical bottles of this prepared sample.

Mr. DORAN. Any question about the request made by Mr. Whissel?

Mr. FLEISCHMAN. Not at all.

Q. When was that?—A. If I recall rightly, it was about March 21st of this year.

Q. So that you sent in, did you not, a portion of that sample of the two bottles?—A. Yes; I received the bottle from Dr. Braun and he indicated—although some one had put another seal on it—I broke this seal, and gave two subdivisions for a check assay.

Q. And you sent these two vials to Mr. Whissel in March?—A. I believe I did. The lawyers directed to whom to send them.

Mr. DORAN. Just mark these two for identification, at this time.

Mr. FLEISCHMAN. Put them in evidence. I have no objection.

Mr. DORAN. I just want to find out about it, if I may.

Q. Tell me which one is the one you sent to Mr. Whissel, if you can?—A. Well, here this bears the regular form of the Department of Agriculture, the official stamp, what we call a "frank," a privilege of sending mail at the Government's expense. This was addressed to Mr. Robert J. Whissel, and this one was packed—

123 Q. Is that the type of bottle inside that you sent to him?—A. Yes; I recognize my seal, the Food & Drug seal. I have my name, that is my handwriting on there. It is labeled "Tablets of digitalis, sample 78,786-D, which is the same number that is on this chart here, and "3-21-41," and that is March 21 of this year, and sealed it up so there would be no question.

Mr. DORAN. Will you just mark that for identification, the one that the doctor has been talking about?

(Bottle marked "Government's Exhibit Number 10" for identification.)

Q. Now, did you send a portion of that sample, Government's Exhibit Number 3, to anyone else?—A. Yes.

Q. To whom was that, Doctor?—A. That was sent to Dr. C. W. Chapman, whom we had requested to do a check assay.

Q. And that is the Dr. Chapman who is here in Court?—A. Yes.

Q. When did you send that to him, Doctor?—A. I sent that to him a few days afterwards, when it is customary, when a concern involved in a shipment asks for a subdivision of a sample, as it was in this case. We asked for an outside test to be made and so on that date, I believe I wrote Dr. Chapman asking him would he please conduct such a test, and I believe he replied in the course of two or three days that he would, and some days after I sent him the sample bottle, which was a sample prepared exactly the same time as I recall.

Q. And is that the one?—A. As far as I know, at least, the corks are the same, and identically sealed. There were three made, and where the third one is I have no knowledge of that.

124 Q. These tablets that you just referred as being sent to Dr. Chapman, you sent them out?—A. Yes; and it was kept tightly stoppered and under refrigeration.

Q. And those sent to Mr. Whissel, and Dr. Chapman, they were sealed and properly stoppered?—A. Yes; that is true.

Mr. DORAN. Mark that for identification, please.
(Sample bottle marked "Government's Exhibit Number 11" for identification.)

Mr. DORAN. I think that is all.

Cross-examination by Mr. Fleischman:

Q. Now, that you have made it so clear by the map that everyone in the room except myself understands it—

Mr. DORAN. I object to such comment.

Mr. FLEISCHMAN. I am paying him a compliment.

Q. You are an expert, Dr. Miller, you are an expert, and hold yourself out as such?—A. One question at a time, please. What do you want me to reply to?

Q. I want you to reply to the question, if you hold yourself out as an expert?—A. No; I don't set myself on a pedestal. I am considered as such by some people.

Q. Well, the Government puts you on the witness stand as an expert, you know that?—A. I suppose so.

Q. And, therefore, I assume you are an expert, that is correct.—A. I cannot be responsible for what you assume.

Q. Well, are you an expert?—A. I consider myself as an expert, I said.

Q. You, therefore, express opinions on matters pertaining to this digitalis, and its potency and what should be done, and anything else?—A. One question at a time, please.

125 Q. Well, answer it any way you please.—A. I express opinions on methods; yes.

Q. And, of course, one of the things you are interested in is the protection of the citizens of the United States, the health of the citizens, by the use of digitalis. That is an important thing.—A. In just what way, may I ask?

Q. In any way you think of it, it is of vital importance; the health, that is what you are there for, to protect the health of our citizens.—A. My job on the digitalis is to assay the digitalis, to see if it complies with the label. I turn over my findings to another division. My job is to assay the digitalis.

Q. What I am trying to get at, if you knew of your attention was called to the fact that digitalis was being sold under a label containing what this label said in this case, and the contents you found was only half the strength and you knew there were millions of these being sold, you would try to gather them in to protect the health of the people?—A. It is my job to report to my superior officer that this material was half strength.

Q. Do you know if any of the millions of these tablets were gathered in or not?

Mr. DORAN. I object to that; that is something not in evidence.

The COURT. I think the answer to the question will obviate the necessity for your objection. I think the doctor will say how many were out.

Mr. DORAN. All right.

Q. Doctor, will you try to assume that there were at least one million of these tablets?—A. You are asking to do that?

Q. Yes.—A. Yes.

126 Q. You are giving us opinion all the way through here.—A. Yes; I will be glad to assume that.

Q. And if you assume they were mailed out in just the quantity of one thousand, there were 999,000 more out, wouldn't it be your duty to communicate with the Government to grab all the rest sent out?—A. No; you are going too far. My duties are the assaying of digitalis and not my duty to recommend to the Government as you suggested.

Q. If you saw poison out in one bottle and you knew there were another thousand pounds out in bottles of that kind,

wouldn't it be your solemn duty as a citizen, as well as an employee of the Government, to try and correct that, wouldn't it be your duty, whether you are paid for it or not?—A. I don't poke into other people's business.

Q. But you are being paid by the United States Government to poke into the business of—A. I am hired to test digitalis.

Q. If the digitalis was bad, wouldn't you go one step further to see about taking in the rest of them?—A. That is not my job.

Q. That is what I conceive to be your duty as a chemist and as a citizen of the United States, a public duty, that is not your job if it is bad, the digitalis?

Mr. DORAN. Is this a summation or what? I don't get the point, and I will object to it.

The COURT. Sustained.

Q. Let me ask you a fair question: Will you again assume, I want you to assume again now that this digitalis that you tested was made by a concern named Arner & Company?—A. All right.

Q. And there were a million made of them, assume that.—A. I will assume that.

127 Q. And assuming for the purpose of argument that it was ultimately sold and shipped to the Buffalo Pharmacal Company, and assuming further that the Buffalo Pharmacal Company took it, and say it was turned over to a doctor out in Ohio, who testified here, Dr. Tagett.—A. Am I to assume that a million were made, they were made by the Arner Company, and they were turned over to the Buffalo Pharmacal Company?

Q. Part of them.—A. And they did nothing to it?

Q. Packaged in the way you found it.—A. That is, packed in the bottles?

Q. And stoppered in the way you say it was stoppered?—A. Yes. Now, I am with you.

Q. Then it went in that way over to Dr. Tagett in Ohio and he used it for two months, as I say, using it on a number of patients, used about half the bottle, approximately 500 tablets. I want the benefit of your opinion as to what the Buffalo Pharmacal Company did under the circumstances, or didn't do, that you in their position would do or not do.

Mr. DORAN. I object to the form of the question as calling for a conclusion, and assuming facts not in evidence, and again the question of good faith of the Buffalo Pharmacal Company is not an issue.

The COURT. On your first objection, the question would call for an opinion of an expert, on an assumption of fact. As to the next objection, that is entirely immaterial, the question of good faith is not here.

Q. Let me put it in a simple form. You have been here in this court room.—A. Yes.

Q. And listened, you have listened, and last night you went into it very thoroughly, a discussion of the evidence with Counsel.—A. Did we?

128 Q. Yes.—A. We discussed it some.

Q. Well, you had a right to. Based on the evidence that you heard, will you tell me how you or the Buffalo Pharmacal Company under those circumstances could have done or not have done?—A. I know very well what I would have done.

Q. What?—A. I would have had a check—

Mr. DORAN. I object to the question, the question of good faith is not an issue here.

The COURT. I think that is so.

Mr. FLEISCHMAN. The witness is awfully anxious to answer it, and I think he should; I would like his answer.

Mr. DORAN. Not an issue in this case.

The COURT. Sustained.

Mr. FLEISCHMAN. Very good.

The COURT. On the question of good faith, that is not an issue here.

Q. You say you were also employed by the Upjohn Company?—A. Yes; in the sense that I was the research fellow, never considered a regular employee. I worked in their laboratory, paid by them, but always considered as a fellowship.

Q. The Upjohn Company is a large concern?—A. I think so.

Q. Am I correct in saying that the firm of Parke-Davis is a very large concern?—A. Yes.

Q. Who manufacture digitalis tablets?—A. I understand they do.

Q. You said that you were a member of some committee which properly claimed credit for and distinction, that you were 129 a member of the Revision Committee?—A. No, I cannot be. Mr. Campbell, my chief, he holds the view that the Pharmacopeia is the book of standards which is recognized, a law that we enforce. We cannot make the law. I can advise when requested to, and I do it.

Q. When there come a time when you have got to get a very expert opinion about the contents of digitalis, you go to the master, Mr. Chapman, and he is very highly regarded?—A. I think a lot of him personally, he is a personal friend of mine.

Q. Am I correct in saying that Mr. Chapman is the cream, so to say, of those who assay digitalis?—A. The truth is this, that he is the only man not connected with a manufacturer's force. We cannot go to Parke-Davis or Upjohn to check on their prod-

ucts. Dr. Chapman is a professor of pharmacology, and the only one now equipped to qualify to carry out an assay, who is not connected with a company.

Q. Will you listen to my question. Now, will you answer my question: Is there any question about the ability of Dr. Chapman as being one of the ablest men in the United States on the question of the analysis of digitalis?—A. No.

Q. You seem, you say as if in doubt. Will you tell me if you mean it, is it no or yes?—A. It is no.

Q. You mean that as being the fact?—A. I said No.

Q. All right. Well, who else is it that is outstanding in the field, outside of yourself, in digitalis?—A. Dr. Braun and Dr. Chapman and Dr. Thompson and Dr. Haag, of the University of Virginia. I know a number of men in the industry, Dr. Nelson, a number of assay men. I can name a lot of them.

Q. Haven't you in your profession some outstanding figure that you apply this expression to "they are the last word"?—A. Oh, no.

Q. How about Dr. Gold of Cornell University?—A. I certainly would put him in among those.

Q. Among who?—A. The outstanding men.

Q. Yet you didn't mention his name?—A. I think I said that I wouldn't put him in among the names of the frog assay men, he doesn't even have a good frog tank.

Q. He hasn't?—A. No.

Q. You have a good frog tank?—A. Yes.

Q. Therefore, you are an expert?—A. That is part of the equipment to carry out the test.

Mr. FLEISCHMAN. And Harry Gold, he hasn't one?

The COURT. We will take a five minute recess.
(Short recess.)

Q. Where we left off, as I get it or remember it, rather, it was Dr. Gold, in your opinion, is not such a good expert, because he has no tank?—A. He is an expert on cardiology, the study of the human heart.

Q. One of the best in the country?—A. Yes.

Q. But he hasn't a frog tank?—A. No; he knows nothing about the frog method.

Q. He doesn't?—A. Not very much.

Q. Will you tell this jury what college it is that Dr. Harry Gold is connected with, not as a physician, but as a chemist?—A. I think it is Cornell University.

Q. Is it your opinion that the Cornell University has one of the best recommended medical schools in the world?—A. Well, I went to the one that I liked.

Q. Tell me this—you are sold and when I say "sold", you believe in the frog method of testing completely?—A. I think it is a very good method.

131 Q. And you know they don't recommend the cat method?—A. I am not sold on the cat method.

Q. And is that the reason that you think that is not, as a good expert?—A. No, no.

Q. Well, do you know Dr. Marvin Cattell?—A. Well, acquainted with him.

Q. What college connected with?—A. He and Dr. Gold in one department.

Q. Is that department in the medical school of Cornell University?—A. No; the Department of Pharmacology, in Cornell University.

Q. And that is in New York City, and not in Ithaca?—A. It is.

Q. And it is located in the Bellevue Hospital?—A. I have been there, I know it is a medical school.

Q. You have been there?—A. Yes.

Q. Both he and Dr. Cattell connected with the Cornell School?—A. Yes.

Q. You never saw the tank?—A. They described it to me.

Q. And from the description, you didn't like it?—A. No.

Q. What does that mean?—A. No.

Q. You didn't like it from the description?—A. I don't want to say that. Dr. Gold and I are good friends.

Q. But you told us, even if a good friend, you told about the tank which you didn't know anything about, his frog tank, still your answer was that it was not a good frog tank?—A. Yes; that is right, and I still believe he hasn't.

Q. Do you know Dr. Eggleston?—A. No.

Q. Do you know his work on it?—A. He published "Digitalis" in 1916, a long time ago.

132 Q. Isn't that the accepted method today?—A. Not in my opinion today.

Q. But it is the official textbook in many medical schools?—A. Yes.

Q. What school was yours?—A. The University of Rochester.

Q. How about Dr. Hatcher?—A. He is quite an old gentleman.

Q. But known as the greatest heart man we have ever had?—A. No; I don't think so.

Q. Do you know the Hatcher method?—A. Not specifically. What good in asking me?

Q. Do you know the different methods of assaying digitalis?—A. I don't think I know that one.

Q. Well, he wrote a book on it.—A. He wrote a paper. I don't know such a thing as the earliest method of digitalis.

Q. Did you read the book that I gave you yesterday?—A. I glanced at it.

Q. Do you know about the earliest body-weight method of administering digitalis?—A. Yes; that is another matter. Was that in the book?

Q. You read the book only yesterday.—A. I said I glanced at it. I didn't read that part of it.

Q. We won't stop you from reading it. Have you since found out the doctor that wrote it?—A. It was "Medicine Marches on" by Dr. Piodolski. I never heard of him.

Q. Have you found out, is it correct that he is president of the New York State Physicians or what is it?—A. I think you ought to be more specific, I would like to have you be more specific.

Q. Just what society is it?—A. There are a number of societies.

133 Q. What is the leading medical society in the State of New York?—A. I don't know.

Q. Isn't it the New York State Medical Society?—A. I suppose so.

Q. Isn't it the leading one?—A. A number of New York societies.

Q. I am talking about the State of New York.—A. New York City, and that is in the State of New York, I believe.

Q. Do you want to read something?—A. Yes.

(Witness reads:) This is rather ancient history.

Q. When we take medicine we start out with ancient history?—A. Yes.

Q. Digitalis is comparatively new?—A. No.

Q. And its application in the United States was generally recognized by medical men not earlier than 1907?—A. No; much older; described by Withering, 1775.

Q. When was it accepted in New York State? Read it to the jury.

Mr. DORAN. I object to that.

The COURT. Sustained. You are asking him to read from a book by the President of the New York State Medical Society.

Q. You said that this doctor described it when?—A. 1775, it is my understanding.

Q. Let me ask you this question: Now, as a matter of fact, as far as medicine is concerned, and particularly digitalis, was that medicine known as digitalis by that doctor, and it was not accepted by the medical profession until Dr. James McKenzie, a high-grade heart specialist, described it in 1905?

MR. DORAN. I object to the statement of counsel.

134 Q. Is that a fact?

THE COURT. That is something you apparently are reading out of a book of the president of the New York Medical Society, and that does not make it an authority.

MR. FLEISCHMAN. I want to lay the foundation for something, he said it is an ancient medicine commonly used.

THE COURT. That is all right, if you don't read something from that book. You can ask the witness any question that you want to.

Q. As a matter of fact, do you know from your reading, as to when digitalis was accepted in the United States by doctors generally as being a heart stimulant?

MR. DORAN. I object, not proper.

THE COURT. I will receive it.

A. I would hesitate to say just when it was. I wouldn't trust my memory on that.

Q. What committee was that you were telling about that you have the honor of being a member?—A. It is the so-called "Steaming Committee" under the Head of Dr. Nelson of Toulane University.

Q. Have they any connection with the Department of Agriculture?—A. No.

Q. Do you know Marvin R. Thompson?—A. Yes.

Q. Do you know the committee over which he is chairman?—A. I think he is head of several committees.

Q. You heard me mention the balance?—A. I don't know that committee.

Q. Well, is this an official pamphlet so far as you know, that I am now showing you? Will you tell me what it is? I think it is written on the top, if that is of any assistance.—A. May I have the question?

135 Q. Is that the official paper, and if so, by whom, as far as you know, was it issued?—A. I can read it?

Q. Yes. Couldn't you read it during the recess, wouldn't that help you more?—A. I would be glad to.

Q. Well, sir, do you do the American Drug Manufacturers' Association?—A. I know there is such an organization.

Q. Has that anything to do with the Government, this lot of men gathering to make revisions of laws?—A. I suppose they submit suggestions.

Q. Isn't it a fact that Dr. Thompson is a member of the official Revision Committee of the Government?—A. No.

Q. Are you sure?—A. Quite sure.

Q. Are you quite sure, or—A. Let us look in the book.

Q. Is the Dr. Thompson in this article one of the members—

A. If he says he is, then I am quite willing to accept what you are telling me is true, but I am most positive not a member, and an auxiliary member, but not a member of the 50.

Q. Will you read this during the recess?—A. I will be glad to read it.

Q. This standard is used to determine the potency of drugs you have produced here. You don't know about it?—A. Oh, yes; prescribed in the Pharmacopeia.

Q. You didn't make it up, the tablets, the drug itself was not made up by you?—A. The standard powder, made up from the standard powder.

Q. Who made up the standard powder?—A. I heard a long discourse on that in a case we had in New York.

Q. Please, Doctor—A. Well, you are asking me.

Q. Will you please tell me, I want an answer to my question, who made up the tablets or whatever else you used in 136 that standard by which you judge the potency of the drug in question here?—A. To the best of my knowledge, that was made up under the direction of the Board of Testing of the Pharmacopeia.

Q. But you had nothing to do with it?—A. No; I couldn't have.

Q. And you don't know then, you are not the expert that mixed it up?—A. I heard a man testifying under oath.

Q. But you didn't do it?—A. No.

Q. You had no part in it?—A. No.

Q. All you know then is something given to you, and you accepted it?—A. Yes; and—

Q. That is an answer. Moisture has to do with the effect on digitalis, moisture, that is a very important thing in lessening the potency of the digitalis?—A. What is the question?

Q. Moisture has considerable to do with the lessening of the potency of this drug, assuming that it?—A. I won't be sure that I know what you are asking me. May I have it again?

Q. I will put it another way. If there is more moisture in there; if there was 8 percent moisture in the digitalis, it would lose its potency faster than if it had four percent?—A. Not altogether my experience. It has something to do with it, but not altogether.

Q. What has it to do with it?—A. I couldn't answer you that. You want a specific example—

Q. No, no. Is it an atmospheric condition?—A. What do you mean by an "atmospheric condition"?

Q. We will pass that.—A. I don't know.

Q. Refrigeration?—A. I don't think so.

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Q. Why put it in the refrigerators, if no use for that?—
A. Simply because it is liquid.

Q. Not because it is in a refrigerator at all?—A. That is where we keep it locked up.

Q. Can you tell us if light, moisture, and refrigeration have no effect on the potency of this particular drug here?—A. Now, I haven't said that.

Q. Will you please tell us what you do?

Mr. DORAN. I object on the ground there is no question asked. It is impossible to know from that.

Q. I will ask you this one: Will you tell this jury, please, what elements will reduce the strength of the digitalis?—A. Well, I think cooking it would.

Q. You think it would?—A. Yes; I think it would, to my certain knowledge. I cannot say if anything else.

Q. Then we have it cooking so far, that you have any knowledge of, that is the only thing that will reduce the potency of digitalis?—A. The only thing I can now figure on.

Q. And you can testify only as to what you know, that is right?—A. Yes.

Q. Will you please explain to this jury why it is that this liquid digitalis loses its potency faster than the dry digitalis?—A. I wish I could.

Q. Do you mean that as an expert you cannot answer that?—A. No.

Q. But it does lose its potency faster than the dry digitalis?—A. Yes.

Q. Did you hear the expert on the stand yesterday say it was as high as 70 percent?—A. I did not understand just what he said.

Q. He is an expert, too, isn't he? Do you mean you couldn't understand one another?—A. I didn't understand him; no.

138 Q. Did you hear him say that liquid digitalis loses 50 percent, and didn't I say it was about 70, and he said, "Yes"?—A. Do you mean 70 percent strength down?

Q. 70 percent strength down.—A. You said both on that. I would like awfully well to answer your question.

Q. I hope so. Did you hear your expert on the stand yesterday say that the potency, the strength of the digitalis would be diminished as much as 70 percent in the liquid?—A. I didn't understand that way at all.

Q. What is the expert you are talking about?—A. I believe you are thinking of Dr. Braun.

Q. I don't think so. Wasn't it Mr. Berman? Well, Dr. Braun, whose place you take when he goes on a vacation?—A. Yes.

Q. He is your superior?—A. No.

Q. Well, we will say your equal, then?—A. Yes.

Q. But you only make this test when Dr. Braun goes on the vacation time?—A. Yes; that is, his duties.

Q. Now, with this vast experience of 18 months on digitalis—
A. Concentrated research.

Q. You have found, the only thing you know of that will reduce the potency of it is cooking?—A. My commission has not been on its strength or why it goes bad. My attention has been directed toward making sure it does go bad. A lot of this, a lot of it is due to faulty manipulation in these tests.

Q. I don't quite follow you.

Mr. DORAN. I think we have a question rather than a discussion.

The COURT. All right. What is the question? Reframe your question, please.

139 Q. As I understand it, with your 18 months' experience as you have described it, you have only found one element that goes to reducing the potency of digitalis and that is by cooking; is that right?—A. That is as I would put it, or figure it, that is one thing I can say that I know will spoil it.

Q. Now, is it or is it not a fact that liquid or tincture of digitalis does lose its potency to a greater degree than the tablet form of digitalis?

Mr. DORAN. I submit that is the identical question just answered two or three times.

The COURT. I think he has answered that.

Q. What percentage of digitalis, as compared with the digitalis in the tablet form, how much faster does it lose its potency and what causes it to lose it?—A. One at a time, please. The first one is what?

Q. What causes the liquid digitalis to diminish or to reduce its strength faster than the dry digitalis?—A. I wish I knew. I don't think anyone knows.

Q. You mean that you, and you consider yourself an expert, to say you think that nobody knows?—A. That is right, that is the result of my experience.

Q. Now, there isn't any question or doubt, is there, in this physical fact that the two exhibits marked for identification, sent out by you, one to Dr. Chapman and one to Mr. Whissel, contain a part of what was taken from Dr. Tagett's office?—A. You want to know if in this matter I had anything to do with this matter as represented by part of the contents of that bottle?

Q. Yes.—A. Personally I testified that I personally took from this bottle the tablets to put in these bottles.

The COURT. Is that part of these tablets there?

The WITNESS. That is right.

140 Q. Are they properly packed as they are here?—A. They are tightly stoppered.

Q. This was not done by the defendant?—A. I put the stopper in personally.

Q. That is the way it should be, with the cotton on it, to allow for any foreign substance—A. So they won't rattle around and break up.

Q. And that is the only reason?—A. Yes.

Q. And it is not for preventing the air or moisture getting in? A. No.

Q. Are you sure about that?—A. Quite positive; never even thought of it.

Q. And you, an expert, say that it would have no effect if this bottle were not stoppered at all, no effect on the digitalis if it wasn't in there, assuming that it stood without anyone moving it, so that the contents would not rattle around?—A. Let us have that question, please.

The COURT. Does it make any difference in case the cork is in or not?

The WITNESS. It might stand out and the rain come into it.

Q. Do you say that moisture has no effect?—A. I don't know that it would cause it to deteriorate.

Q. Then why put in the cork, except for anything like the rain causing it to become wet?—A. Personally, I put in the corks in these samples so that I would be sure when they got to Mr. Whissel and Dr. Chapman they would have the tablets that I put in.

Q. That is the only reason?—A. It is a good one.

Q. And it wasn't that it loses its potency at all?—A. I feel that they are peppy tablets; that is my feeling.

Q. So that the reason that you put the cork in was only because it would keep all the contents without rattling around, and the fact that it rained in there or anything, that couldn't make any difference?—A. I didn't say that.

Q. What difference would it make if it rained in there?

Mr. DORAN. I object to that—

The COURT. No, no.

Q. What would it do, if this moisture got in there?—A. I imagine it would disintegrate the tablets.

Q. Then the moisture has something to do with it?—A. You wouldn't be able to tell the tablets he had in it, all mixed up with one another.

Q. Now, did you ever help in the cat test?—A. Cat-eye test, for some drops you put in the eyes.

Q. That is all you know?—A. That is one. There are several cat tests.

Q. Don't you realize that we are engaged here in determining and the particular determination now is digitalis, and not interested in the cat-eye test or anything else?—A. I merely wanted to be sure you were talking about digitalis, I don't want to be led into something I am not sure of.

The COURT. Well, it is digitalis.

The WITNESS. Yes; I heard of the cat-test.

Q. Well, on digitalis, that is all.

Mr. DORAN. I submit he doesn't need any cautioning there, and I object to it.

The COURT. The question is, did you ever hear of the cat test as applied to the test on digitalis?

The WITNESS. The answer is yes.

Q. You know there is a school now on the revision committee, which you talk about, which says that the frog test is no good, and to substitute the cat test?

142 Mr. DORAN. I object on the ground that Congress has set a test which it is necessary to follow, and there isn't any other test to follow.

The COURT. His ultimate object is to object that the frog tests is of no value, and whether it falls short, that is another question. The people have a right, regardless of the fact that Congress prescribed it, he would have the right to demonstrate by experience. I will receive it.

Mr. FLEISCHMAN. He was talking about the Revision Committee. I am trying to prove that very fact.

The COURT. I will allow it.

Q. We are talking now about the cat test. Were you present at any meeting of the Revision Committee?—A. No; I am not a member of that committee.

Q. Who was connected with your department when they revised the workings of the Revision Committee?—A. Who was connected with our department when revised?

Q. Yes.—A. Dr. Braun and Dr.—

Q. Are they on that committee?—A. None of us are.

Q. Is Cronin on the committee?—A. No.

Q. He is not a physician but a lawyer?—A. I think so.

Q. Do you know if Dr. Chapman is on there?—A. Yes.

Q. Is Dr. Gold on there?—A. He is a member of that committee; yes.

Q. Now, I refer you to the book which you have been reading, the Pharmacopeia of the United States, to the pages which you referred to, the one page which is 137, and I ask you if that

is not a fact that it says "storage to preserve powdered digitalis in waterproof and air-tight containers and protect it from light"—A. Yes.

Q. Do you know it is in there?—A. Yes.

143 Q. Why did they put that in there, will you tell us, if these elements have nothing to do with affecting the potency of digitalis? If not subject to those things, it was just nonsense then?—A. Just a precautionary measure.

Q. All right, then, if not required, why does your book, the bible of chemistry, as I recall it, require those things to be done?—A. I don't know why they are required, but I heard a lot of manufacturers complaining against it.

Q. What manufacturers have you heard complaining of it?—A. Lilly.

Q. Who else?—A. That is all.

Q. How about Parke-Davis?—A. I don't know.

Q. Is that a big house?—A. Why, yes.

Q. Don't you know they are putting out big sales?—A. Yes. I said I heard a complaint of the Lilly Company and also from Sharpe & Dohm.

Q. Complaining about what?—A. About being unnecessary.

Q. But your book over here that you say is greater than all the experts, this has to be followed, the law requires it?—A. That is a precaution. They say it goes farther than necessary, they want to make doubly sure.

Q. And you say, as an expert of 18 months' experience, that is not necessary?—A. I don't say it is not necessary.

Q. Do you know Dr. Taylor, the chief chemist of Parke-Davis?—A. Yes.

Q. Is he a very able man?—A. A good chemist.

Q. In the commercial field, Dr. Taylor stands supreme?—A. A good chemist.

Q. Read this letter from him. I will ask you something about it—first, do you recognize his signature?—A. I believe I do.

This, of course, refers to liquid.

144 Mr. DORAN. I object to taking the time of the jury and the witness in reading some letter. And of course, we can all get letters from 100 doctors.

The COURT. He recognizes him as a good chemist. Under that theory you might bring in a letter from any good chemist. I don't think that is the proper way of testing his qualifications.

Mr. FLEISCHMAN. Allow me an exception.

The COURT. Yes. I want to make it clear what I am ruling on, you are showing him a letter from a man named Taylor from Parke-Davis & Company.

Mr. FLEISCHMAN. That is right.

Q. Have you read the letter?—A. No.

Q. Please read it.

Mr. DORAN. We are wasting time here.

Mr. FLEISCHMAN. I want to ask him now that he reads the letter, that he admits Taylor is a great expert.

The COURT. He said expert, a good expert.

Mr. FLEISCHMAN. I assume he is an expert?

The COURT. Not a great expert.

Q. Do you know Dr. Taylor personally?—A. Yes.

Q. And you in your business, or in the Government business on the question of chemistry, he is recognized as an authority?—A. You realize, of course, that I cannot recommend him—

Q. Not asking you that: I am asking you to give your opinion on this.

The COURT. Let me see it. How do we know the purpose of this letter? I suppose it was written to you in the course of the trial. Mark it for identification.

145 (Letter from Mr. Taylor marked "Defendants' Exhibit B" for identification.)

Q. Would it help you any if you read from the writings of the chief chemist of Parke-Davis & Company, Dr. Taylor, as to what his opinion is?

Mr. DORAN. That is objected to as an improper method of cross-examination. There is a definite way that an expert can be cross-examined.

The COURT. I will overrule the objection. I think the answer will obviate it. Is he recognized, that is, Dr. Taylor, as an eminent expert, and if so, he might very properly say so.

The WITNESS. What is the question again?

The COURT. Would it help you to read Dr. Taylor's writing, as chemist in Parke-Davis & Company, in forming an opinion on the effect or the different effects on digitalis?

A. I am a scientist, I am interested in data.

Q. Then it wouldn't help you?—A. No.

Mr. FLEISCHMAN. That is the answer. That is all.

Redirect examination by Mr. DORAN:

Q. So there won't be any confusion on one or two questions in the cross-examination, the "U. S. P." or "U. S. Pharmacopeia" is referred to, or was rather referred to as a United States document. That is not so, is it?—A. No.

Q. It is put out by an entirely separate group?—A. Yes.

Q. It is, however, recognized by the Food & Drug Act as the official compendium?—A. That is right.

146 Q. Now, Doctor, assuming that Exhibit No. 3 in evidence, the bottle of digitalis tablets, were shipped from

Buffalo, New York, to Rock Creek, Ohio, on or about June 8, 1940, in a bottle sealed with a cap, kept in the office of Dr. Tagett, in his drug room, at all times, capped, that he kept that cap thereon except in the instances when the doctor removed it for the purpose of taking a few tablets out, and that that same bottle with the remaining tablets contained in, were picked up or purchased by Mr. Faries on February 29, 1940, what is your opinion as to whether or not an appreciable amount of deterioration might have taken place between January 8 and that date under those circumstances?—A. Under the circumstances that it was shipped in January, and kept in the office in good condition, kept stoppered?

Q. Yes.—A. And then collected February 29th and then I assayed some.

Q. We will assume further that it was kept sealed until the time you assayed it, which I believe you said it was—A. March 11th, 1940.

Q. In your opinion would there be any appreciable amount of deterioration taking place in that period in the powder or in the digitalis tablets?—A. No; I know of no reason why—and I think it was absolutely answered—that it would deteriorate in that time.

Mr. DORAN. All right.

Re-cross-examination by Mr. FLEISCHMAN:

Q. I show you this pamphlet once more, and assuming that this is the actual communication by Dr. Marvin R. Thompson, the chairman of this committee, and you say anything he 147 said would be true, if Dr. Thompson said it, you know it is true?—A. He is a reputable man, but this is not his signature.

Q. I say, assuming it is an official document, and he says—

Mr. DORAN. I object to that. We don't know anything about who typed it or where it was typed or under what circumstances. You cannot get it in indirectly in that manner.

Mr. FLEISCHMAN. All of which shows at this time that Dr. Thompson is a member of that Revision Committee.

A. In what connection? He is on a lot of committees.

Q. You take this between one and two o'clock or before that time and read it, and I will ask you this.—A. I will be glad to.

Q. It seems you answered the question whether there can be deterioration in that period when it traveled from Buffalo to Dr. Tagett, and in the way described by the District Attorney, and you said No.—A. Yes.

Q. Now, assuming that the same substance that you have here was examined by Dr. Thompson on June 4, 1940, and he says he found it true within the limits of—

Mr. DORAN. I object to any assumption.

The COURT. I will sustain that. I will instruct the jury in this case that Dr. Thompson reached that result.

Q. Will he be here this afternoon?—**A.** Yes.

Mr. FLEISCHMAN. That is all.

The COURT. That is all. We will recess until 2 p. m.

(Recess until 2 p. m.)

148 (After recess, 2 p. m.)

LLOYD C. MILLER, resumed, testified further as follows:

Re-cross-examination by **Mr. FLEISCHMAN** (continued):

Q. Dr. Miller, did you, during the recess, read the paper I showed you?—**A.** Yes.

Q. Do you recognize it as the document from the committees that you spoke about this morning?—**A.** No; I spoke about several committees. This one is a paper, I take it, which represents a report by Dr. Thompson, as the chairman of the committee, apparently to the American Drug Manufacturing Association, an association of drug manufacturers, and it does not include, it includes relatively few of those who have the right to serve on the—

Q. Is he a member?—**A.** No; an auxiliary member, not a member.

Q. Does this help you to determine whether the potency of digitalis is affected by elements other than your answer to me before, that is, the cooking process?—**A.** No; this doesn't mention it.

Q. This doesn't help you at all?—**A.** This doesn't have anything to do with it.

Q. Does this help you to determine whether or not digitalis loses its potency to the extent of 50 to 70 percent, as testified by your associate yesterday?

Mr. DORAN. That is objected to, it is assuming facts not in evidence at all.

The COURT. Sustained.

Mr. FLEISCHMAN. I respectfully except to Your Honor's ruling. That is all.

149 **CLIFFORD W. CHAPMAN,** called as a witness on behalf of the Government, and sworn, testified as follows:

Direct examination by **Mr. DORAN**:

Q. Dr. Chapman, where do you live?—**A.** Baltimore, Maryland.

Q. What is your occupation?—**A.** Chemist and professor in the School of Pharmacy, University of Maryland.

Q. How long have you been a professor in pharmacology in the University of Maryland?—A. Since 1938.

Q. What is pharmacology?—A. Pharmacology is the science which deals with the effect of drugs on normal animal tissues, and normal animals.

Q. What education did you have in pharmacology?—A. I graduated from the University, and obtained my Doctor's degree in pharmacology and chemistry in McGill University, in Montreal.

Q. Does that complete your education in that line?—A. As far as academic education is concerned.

Q. What experience have you had, then, after you completed your education?—A. I have had about thirteen years experience in pharmacology, especially in the line of bacteriology, with the Canadian Government in Ottawa, and a short time with the Federal Government in Washington, as an independent associate not connected with anybody including the Government.

Q. How long as an independent assayer?—A. Since I have been in Maryland; thirteen years.

Q. As a bacteriological assayer, have you made a number of assays on digitalis?—A. Yes.

Q. And you, I take it, in the course of your educational experience, have you become familiar with the United States Pharmacopeia?—A. I am a member of the Revision Committee of the United States Pharmacopeia.

Q. I think you ought to know something about it, then—

Mr. FLEISCHMAN. We agree on that. We stipulate as to his qualifications, that he ought to know what he is talking about.

Mr. DORAN. I simply want to bring out what the Revision Committee of the U. S. Pharmacopeia is.

The COURT. Go ahead.

Q. What is the Revision Committee?—A. The committee is comprised of 50 members elected from delegates appointed by members who are in medical institutions, like medical schools and societies and schools of pharmacy and pharmacy societies throughout the United States. There are at this time, I believe, around 3,000 member delegates, and they elect 50 on the Revision Committee, who have charge with the development of standards to be put into the United States Pharmacopeia.

Q. The United States Pharmacopeia, by the way, Doctor, has been in existence how long?—A. Since about the beginning of the 19th Century, about 1812, I think. This is the 11th revision, and usually decennial revisions.

Q. Tell us briefly, what is contained in that book, and which is published, as I understand, every ten years.—A. It contains a series of articles known as the monographs, dealing with vari-

ous drugs used by the Medical profession. It details the standards and methods of tests for each one of these drugs.

Q. Now, I referred this morning, and it was received in evidence, here, a portion of the 11th edition of the United States Pharmacopeia, providing for the test or assay for digitalis on page 397 and also pages 136 and 137. You are familiar with it?—

A. Yes.

151 Q. And those are the pages in that edition of the Pharmacopeia; where the actual test or assay for digitalis is found, and the standard of potency for the digitalis is found on pages 136 and 137, is that right?—A. Yes; and a section on the tincture on page 485.

Q. But with respect to powdered digitalis, these are referred to as the standard in the test?—A. Yes.

Q. Now the 11th edition we have been talking about of the United States Pharmacopeia, that came out what year?—A. 1936.

Q. And that is, I suppose, that is the usual rule, the United States Pharmacopeia is in existence for ten years?—A. It is still in existence.

Q. When will the next convention be?—A. Another one is in the process of preparation at present.

Q. The next revision will come out when?—A. That is difficult to say. They hope to have it out this year.

Q. Now, approximately, if you know, how many assays of digitalis have you made?—A. That I have made? I made about 100 during the course of the last year and that is about the average number I do.

Q. Now, digitalis, by the way, Doctor; comes from what form? I mean by that, it is put in different ways such as the tincture, the liquid form, and the powdered form?—A. You mean for use as medicine?

Q. That is right.—A. It comes usually as tincture and the dry powder.

Q. What is tincture?—A. It is an alcoholic extract of the digitalis leaf.

Q. Is it liquid?—A. Liquid.

Q. And what other form?—A. The liquid extract and the solid extract and also put out in the tablet and pills, and several other forms.

152 Q. Now, you are familiar, I take it, with the actual tests or assays for this powder as provided in the U. S. Pharmacopeia known as the "frog method"?—A. Yes.

Q. By the way, how long has that been in existence, that frog test?—A. The actual method or frogs be used as the test animal?

Q. Well, frogs be used as the test animal.—A. The credit is usually given to Houghton of Parke-Davis as the originator.

Q. When was that?—A. Oh, about 1819.

Q. I suppose to some extent, has there been some change in the method in the test applied through the use of frogs?—A. Certainly, that has been improved.

Q. I suppose that is one thing that you people try to improve?—A. That is our aim, but whether we suggested it or not, I cannot say.

Q. Now, did there come a time, Doctor, when you received, I believe it was in March—correct me if I am wrong—1941, a sample of digitalis powder from the Food & Drug Administration?—A. This one bears my identification number and date and that was received on March 29, 1941.

Q. From the Food & Drug Administration?—A. From the Food & Drug Administration.

Q. And for the purpose of identification, are you referring to Exhibit Number 11 for identification?—A. Exhibit 11.

Mr. FLEISCHMAN. March 1941?

The WITNESS. 3-29-41.

Q. Now, the sample of tablets that you received was contained in the glass vial that is inside that container?—A. Apparently the same vial. It has my number on it.

Q. You put on a number to identify it when you received it?—
A. Yes.

153 Q. Was it sealed, the glass vial?—A. It was sealed and I broke the seal, and it hasn't been out of my possession.

Q. Doctor, did you make a test, of some of the tablets in that vial, which is a part of Exhibit Number 11 for identification?—A. I did.

Q. And in making that test, what was the purpose of your test, or your analysis, I mean by that, to determine the potency or strength?—A. Yes; potency or strength.

Q. Did you use the official U. S. P. method or the frog method in making your test or analysis?—A. I did.

Q. And you followed that as laid down in the U. S. Pharmacopeia?—A. I did.

Q. What were the results of your analysis of the portion of tablets contained in that exhibit?—A. May I read from my report?

Q. You can refresh your recollection.—A. On the tablets 48 U. S. P. unit. That makes the tablet about 48 percent of the labeled potency of $1\frac{1}{2}$ grains.

Q. You mean by that slightly less than one-half strength, Doctor?—A. Yes.

Q. That is the result you arrived at in your analysis, is that right?—A. That is right.

Q. Now, Doctor, I show you Exhibit Number 10 for identification, and which is cardboard box containing a similar glass vial, and ask you to examine that and state whether or not you received that and if so, when?—A. I received on April 2, 1941, apparently the same box or carton.

Q. And from whom did you receive it?—A. S. E. Penick & Company, New York City.

Mr. DORAN. Is there any question that is the sample sent through Penick to Dr. Chapman?

Mr. FLEISCHMAN. That is under our stipulation.

154 Mr. DORAN. You agree that the sample, Exhibit Number 11, was the one received by you from the Food & Drug and sent to Dr. Chapman through Penick?

Mr. FLEISCHMAN. That is right, except that it should be Exhibit Number 10.

The WITNESS. Exhibit Number 10.

Q. That was received in the same condition as the other vial; that is, it was sealed and so on?—A. Sealed with an official label bearing Dr. Miller's signature, or what I assume is his signature.

Q. Did you make a test or an analysis of a portion of the digitalis tablets in that vial?—A. I did.

Q. And did you make this test under the official U. S. P. or the frog method in making your test?—A. I did.

Q. And you followed that as laid down as provided for in the 11th Edition of the U.S. Pharmacopeia?—A. I did.

Q. What were the results of your analysis?—A. This sample assayed 51 percent of the labeled potency.

Q. That would be substantially half strength, is that right?—A. Yes; that is right.

Q. In our layman's language?—A. Yes.

Q. And both samples were digitalis tablets, were they not?—A. They purported to be digitalis tablets.

Q. You found that was the potency or the strength or analysis?—A. According to the official method.

Mr. DORAN. I offer them in evidence as Exhibits 10 and 11 for identification.

Mr. FLEISCHMAN. No objection.

The COURT. Received.

(Government's Exhibits Numbers 10 and 11 for identification received in evidence.)

Mr. DORAN. You may ask.

155 Cross-examination by Mr. FLEISCHMAN:

Q. Dr. Chapman, as a member of the Revision Committee which you speak of, and referring to page 137, which says,

"Storage preserved powder of digitalis in waterproof, in airtight containers, protected from light," you know that, don't you?—A. Yes.

Q. Do you have to do with the preparation of this formula and this statement in that book?—A. No; that was ten years ago, and I wasn't on then.

Q. From your experience with digitalis, it loses its potency under certain conditions?—A. Under certain conditions; yes.

Q. Now, I want you to tell this jury the condition under which digitalis will lose its potency.

Mr. DORAN. What type of digitalis is counsel referring to; the tincture or liquid form, powder or tablet form?

The COURT. Well, the thing is, we don't want to make any general statement that isn't admissible in law.

Mr. DORAN. The question is general.

Mr. FLEISCHMAN. I have allowed him all kinds of latitude without object and now we have—

The COURT. Go ahead.

Q. Tell us what effect the elements will have on any of the different kinds of digitalis, tell us what it is, liquid or what it is as you go along.—A. I wouldn't say definitely what causes the deterioration in digitalis. Apparently by the official method it does deteriorate. The tincture or the liquid forms deteriorate evidently much faster than the dry form, like the powder or like the tablets. There is probably some relation to the water content. For example, with the tincture, where the 156 alcoholic content is 99 percent, there is less deterioration, that is, the 1 percent water, than there will be in the tincture made by the official method which contains 30 percent water. Now, with the solid preparation, when the leaf is gathered in the field, when the digitalis is green and not properly dried, or rapidly dried, it will deteriorate and it will deteriorate in shipment from one place to another. That is why I believe that the U. S. P. states that it must be in an airtight and watertight container. As to what are the causes for the deterioration, that is controversial. For example, one authority on this subject, and several others that I could mention, state that by the cat method the digitalis does not deteriorate but nearly everyone working with the frog method says it does deteriorate. There are other things beside water that might have to do with it. I have to be technical, it is in the hydrogen-iron content.

Q. Will you explain in simple words, if you can?—A. Sugar will ferment in alcohol by the action of enzymes which are contained in yeast. If you kill the enzymes the sugar won't change to alcohol. You have a similar condition with digitalis. The

active principle in digitalis has been shown in some form to be influenced by the enzymes action.

Q. Is that the explanation, the full explanation that you want to give?—A. No; I can go on with that.

Q. But it is a fact, no matter how you prepare digitalis, it does lose its potency under certain conditions?—A. No; I wouldn't say that.

Q. What would you say, you know what I am talking about, and you know what it is about.—A. I say under certain conditions it may lose its potency.

157 Q. Now, Doctor, assuming a batch of digitalis is made up and packed, packed in the same way, and sent out of the factory; no matter where you pick up the sample, if that sample comes from that same batch, you ought to get the same results.

Mr. DORAN. I object to that as a fact not in evidence.

The COURT. I will receive it.

The WITNESS. Does the question stand?

Mr. FLEISCHMAN. Yes.

A. Most probably, but it may be that a bottle was kept in the light and warm. Another one may be kept in a dark place or refrigerated and there would be a difference in the potency.

Q. That applies to either the liquid digitalis or, as you call it, tablet digitalis or pill digitalis or any other form; is that correct?—A. It applies mostly to the liquid. There is some doubt about the other preparations.

Q. Now, you mentioned the name of S. E. Penick, and you made a test for them, which is here on Exhibit Number 10; is that correct?—A. Yes.

Q. Now, do you know the history of that bottle as it came to you?

Mr. DORAN. I think we stipulated that was part of Exhibit Number 3, the original sample. If no question, why not stipulate that?

Mr. FLEISCHMAN. I stipulate, that is agreed to.

Q. Do you know the history of it? Do you know that it came from a Dr. Tagett?—A. No.

Q. It is stipulated in this case that all these samples came from 1,000 pills from Dr. Tagett, who testified this morning. Were you here?—A. Yes.

158 Q. Was that the only test that you made for Penick of pills of that kind or tablets?—A. I make tests for Penick quite regularly.

Q. That is a very large digitalis concern?—A. Right.

Q. Now, sir, did you make a test for them on April 4, 1940?—A. Is there a p. m. number on that?

Q. Yes. What number do you want to refer to?—A. The p. m. number.

Q. The number is 2249, laboratory number 2249.—A. 2249, that sample was received on 6-4-40.

Q. The date returned 6-7-40?—A. That is right.

Q. And that sample was marked number 45313.—A. Manufactured by—

Mr. DORAN. Just a moment; unless the Doctor knows where the sample came from, unless it is connected up, I will object to that.

Mr. FLEISCHMAN. I will connect it up later, but I have to prepare this.

The COURT. I take it what you are attempting to do is to demonstrate that the doctor performed an analysis of pills from the same bottle?

Mr. FLEISCHMAN. From the same one.

The COURT. There is no evidence up to now that it did, unless, of course, that the Doctor can say that it did.

Mr. FLEISCHMAN. I will connect it up later.

The COURT. You cannot do that. What you are trying is to tie up this Doctor as a part of your case without laying the basis for it.

Mr. FLEISCHMAN. Your Honor, I should have to hold this Doctor until after the defendant's case is in.

159 The COURT. Yes; but the matter of convenience does not alter the rules of evidence. I say you haven't laid the basis of proof to show that they came out of this bottle.

Mr. FLEISCHMAN. I don't say out of the same bottle.

The COURT. It makes no difference what you say, it is what the proof establishes.

Mr. FLEISCHMAN. They know what it is.

Mr. DORAN. That is the point. I don't know it.

Mr. FLEISCHMAN. I think you stipulated that with Mr. Wrissel.

Mr. DORAN. Oh, no; I haven't so stipulated, and I think there is a very great question about it, and that is just the point. I can appreciate the fact that so far as holding the Doctor here a day or two pending its being connected up, but I don't want to be arbitrary in this phase of it. The only way it might be done I suppose is to let him testify what his analysis is, subject to being connected up.

The COURT. That is up to you.

Mr. DORAN. I think we will finish our case in a few minutes, and I prefer to have it done in the regular way, and I think the Doctor will be here anyway today.

Mr. FLEISCHMAN. Or if you permit me to put a witness on the stand to lay the foundation, I will be glad to do that.

The COURT. In your case?

Mr. FLEISCHMAN. Yes. May I proceed then?

The COURT. Yes.

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By Mr. FLEISCHMAN:

Q. Will you refer, Doctor Chapman, to that laboratory report, and I will make it simple by showing you what purports to be a photostatic copy of your report to Penick, and I ask you if that is your signature or the copy thereof on the report?—A. I recognize it as my signature.

Q. Will you compare that with what you have and see if that is correct with what you found on that day?—A. This is apparently a copy of the original.

Q. A copy of the original of what?—A. The report which I forward to Penick under my number P. M. 2449.

Mr. FLEISCHMAN. Mark that for identification, please.

(Photostatic copy of report Number 2449 marked "Defendant's Exhibit C.")

Q. Did you hear in connection with any report that you made from any source, that you were investigating a shipment to Dr. Tagett on January 8, 1940?—A. Not until I came into this Court Room.

Q. Now, sir, did you at the time you examined the tablets in this case, did you make an examination for the State of New York for Mr. Slade from these tablets?—A. I know nothing about that.

Q. This is the first time you heard about that?—A. Yes.

Q. Any rate, in so far as the examination of the tablets that you made, as indicated by Exhibit C, you found that those complied with the potency of the product as submitted?

Mr. DORAN. I object to that.

The COURT. I will sustain the objection. There is no proof of what the source of that sample was, and as far as the proof goes, it had nothing to do with this case.

Q. Now, Doctor, you yourself, do you believe in the frog test?—A. I think that is a very good method.

Q. Do you believe in the cat test?—A. I have opposed the cat test.

Mr. DORAN. Opposed it?

Q. That is the matter pending now in your Revision Committee, with you on one side and Dr. Gold on the other?—A. That matter is under consideration.

Q. Is that the reason why they are going to adopt, instead of waiting ten years for the new report, but to try to get it through this year?—A. No; I wouldn't say that, but I know they are anxious to have the pharmacopeia on the whole out this year.

Q. That is to say, instead of waiting the ten years, you want to have one in 1942?—A. Yes.

Q. In other words, six years instead of ten years as you have been doing for a century before?—A. Yes.

Q. Now, Doctor, assume that a shipment of digitalis tablets was made in January, on January 8th, 1940, to Dr. Tagett, and taken by the Government, February 29, 1940, and examined by you in 1941; am I correct on that, April 5, 1941?—A. If you are referring to any particular sample.

Q. When was your first examination of any of the tablets in this bottle made?—A. On 4-29-41, according to the report.

Q. You say "four"?—A. Yes.

Q. Four what?—A. That would be April 29, 1941, the date of the report.

Q. Do you know that Dr. Thompson examined it on April 28, 1941?—A. Dr. Thompson's report on the examination of that sample was addressed to me and dated April 28, 1941.

Q. Do I understand from what you have before you, that you examined subsequent to Dr. Thompson or before?—A. About the same time, the date of my report is the 29th of April. I did the assay previous to that.

Q. Assuming that these tablets were sent by the defendant corporation on January 8, 1940, to Dr. Tagett and that they represent the same tablets which you examined, or made of the same—what do you call that stuff before you get it out of the machine?—A. Granulation.

Q. A batch of it was made in granulation and eventually you get these pills and tablets or what not, assuming it came from the same granulation, which you in June 1940 pronounced it in conformity with the U. S. P.—A. June 1941.

Mr. DORAN. I object to that. I believe it assumes facts not in evidence.

Mr. FLEISCHMAN. Then the Doctor will have to wait.

Mr. DORAN. I cannot help that.

The COURT. The point is, I said it was up to you if you want to receive it, subject to being connected up by other evidence to show this did come out the same batch of digitalis; if you want to receive it, subject to its being connected up, all right, that is up to you.

Mr. DORAN. The question is, I think it can be connected up very quickly.

The COURT. There is nothing that gives me the right to bridge the gap, you are the only one that can do that.

Mr. FLEISCHMAN. Do you want the Doctor to wait?

Mr. DORAN. You have marked his report—

163 The COURT. Let me get this straight. I take it what you want to demonstrate is that Dr. Chapman made an analysis of another sample which did not come out of this bottle, but came out the same batch of digitalis, and arrived at a different result?

Mr. FLEISCHMAN. Yes; and tied closely to a period they were sold to Dr. Tagett, that is exactly it.

The COURT. If you want to take his testimony subject to proof, on that, that is all right.

Mr. DORAN. That is all right, and I am willing to save time to accommodate this witness, subject to being stricken out.

The COURT. Then it will be received on that theory.

Mr. FLEISCHMAN. All right, then, we will start off with that theory.

By Mr. FLEISCHMAN:

Q. Referring back to your report which we have marked here as "Exhibit for identification C", now assuming there was sent to a Dr. Tagett a thousand tablets of digitalis by this defendant on January 8, 1940, and, assuming that from the same granulation as you call it, on the 4th of June 1940 you examined this sample and found that it complied with the requirements of the Government, and assuming that the tablets which were sent to Dr. Tagett were examined on April 5, 1941, by you, and in which you found that their potency was only about 51 percent, assuming those facts to be true that it came from the same granulation that you made the test from, that same granulation, but that the test of the Tagett tablets which were delivered on January 8, 1940, were not examined by you until April 5, 1941, whereas your examination under this exhibit was on April 4, 1940,

64 will you explain to us if you can, what happened to that particular batch—will you tell us what could have happened, assuming these tablets to be of the same granulation, what could have happened at Dr. Tagett's place to produce a loss in potency such as you have testified to here?

Mr. DORAN. I submit that is going far afield. I take it from that Counsel said he has an analysis of a certain number of tablets made by Dr. Chapman, and he wants the Doctor to testify as to what his analysis of these tablets is, and then later show by other proof, show these tablets came from the same batch as the purchase by Dr. Tagett. Here we have a question that assumes a great many other things.

The COURT. It assumes only one that I think is objectionable. You don't know what the report was, but you don't need the Doctor to assume that he has made it.

Mr. DORAN. Ask him what his analysis was.

Mr. FLEISCHMAN. No; I am going farther than that, I am assuming these analyses were made by him and I am assuming the one thing that I will have to prove later, and that is that it came from the same batch, and I cannot do it now. Now, assuming these facts to be so, and something happened to that Tagett bottle, assuming the others were correct, now, can he tell us what happened to the Tagett bottle, so as to reduce its potency, that is what he can give us his answer on.

Mr. DORAN. That was not the question.

Q. Do you understand that to be so?—A. Not the particular bottle.

Q. Well, you say you don't know anything about the 165 particular bottle, but you made an assay of it, you tested it, and found it contained 51 per cent strength. Now, for our purpose we concede that that came from Dr. Tagett. We also have a report from you made to Penick & Company and we will assume it came from the same granulation that the tablets that Dr. Tagett had in his control and custody two months, and if they subsequently dropped off 51 per cent, can you tell the Court and jury what could have caused that drop?

Mr. DORAN. I object to that, that is way beyond what I got. I had to withdraw any objection to any question whether he made any analyses of some other digitalis than that in this case. I am willing to state what it is, if 70, 80, or 90 per cent light. They can prove later that it came from the same batch all right. We will assume it should stay in evidence.

The COURT. If he proves it, that is a matter of proof. He has the right to state in a hypothetical question the basis of his proof.

Mr. DORAN. Well, I object. It is assuming facts not in evidence.

Mr. FLEISCHMAN. If he wants to withdraw.

The COURT. It was withdrawn.

Mr. DORAN. No; I want him to testify to any sample—

The COURT. Am I to understand now that the stipulation was to qualify so you may ask the Doctor now what you couldn't otherwise ask him? You may ask him what the result of the analysis was in regard to this sample, on the basis of Exhibit C.

Mr. FLEISCHMAN. That is unnecessary as I have it in writing.

The COURT. It is not in evidence.

166 Q. When you examined that batch of stuff, or whatever it was, that you got from Penick & Company on the date in June 1940 was that digitalis that you examined?—A. I made no qualitative test to prove it was. I assumed it was a sample of digitalis tablets.

Q. What did the test show on the tablets you examined, in so far as they contained digitalis?

Mr. DORAN. Fix the date, please.

Q. What was the date, Doctor?—A. Exhibit C?

Q. Yes.—A. Received June 4, 1940, and reported June 7, 1940.

Q. What were the contents of that?—A. One tablet contained .78 U. S. P. units.

Q. What does that mean?—A. That means, and I have written in the report, "This sample possesses 80 per cent of the labeled potency of 1½ grains." The U. S. P. permits a 20 per cent minus or plus in the assay methods. Therefore, the potency was at the lower limit permitted by the U. S. P.

Q. But if complies with the law in regard to the law of the U. S. P.?—A. Yes.

Q. That is a compliance?—A. Yes.

Q. Do you know the effect on humans to take too much or too little digitalis?—A. I am not an expert in that field. That is clinical work.

Q. A physician's work?—A. Yes.

Q. Now, I show you a paper and I ask you whether that is in your handwriting.—A. No, this is not my handwriting.

Q. I beg your pardon. You are sure about that?—A. I am quite sure. I am left-handed and I know.

Mr. FLESCHMAN. All right, thank you very much. That is all.

Redirect examination by Mr. DORAN:

Q. This June 1940 analysis that you just mentioned a moment ago, that was 80 per cent and you don't know anything about the history of it, where it came from yourself, except that you got it from Penick & Company?—A. I received a sample from Penick, that is all I know, about what was on the label.

Q. Doctor, assuming Exhibit Number 3 in evidence, a bottle of digitalis tablets, was shipped from Buffalo, New York, on or about January 9, 1940, in that bottle, and that the bottle was stoppered or had the usual plastic top on it, and it was shipped to Rock Creek, Ohio, on or about that date, and received by Dr. Tagett and kept in his office under normal conditions in a drug room, kept by him in his home, and that nothing was added to the bottle, and that the top was kept intact, upon it, except on a few occasions when the doctor may have taken some of the tablets from the bottle for the purpose of giving them to patients, and that same bottle, with the tablets left in it, was picked up on or about February 29, 1940, and kept sealed in the same condition and some of the tablet analyzed between the 10th and 15th of March 1940 have you any opinion as to whether or not there would be any appreciable amount of deterioration that might take place in those tablets between June 8th or 9th, 1940,

and the date of that analysis?—A. The period of about four months?

Q. Well, that would be from January 29th, to the 12th of March, about eight or ten weeks.—A. It is unlikely but there may have been some and I wouldn't venture a statement on it unless I knew the history of the tablets.

Q. I see. It is unlikely in your opinion, you say; is that right?—A. Yes.

168 Q. You wouldn't say, would you, under those circumstances, assuming these same facts, and it was kept under these same conditions, that there would be any likelihood of any deterioration from one hundred or eighty down to forty-eight per cent, would you, Doctor?—A. It is very difficult to make a clear statement as you have to know the history of those tablets.

Q. What is your opinion of whether it would under those circumstances?—A. Digitalis will deteriorate like a great many other things in the course of the first few weeks, or maybe a month, depending on the conditions, and after that the deterioration is much less. If some of that was freshly prepared under the proper conditions, it could go down maybe not as much as from eighty to forty per cent, that is a big in that period of time. If those perhaps had been prepared months before, not likely to drop.

Mr. DORAN. All right, Doctor.

Re-cross-examination by Mr. FLEISCHMAN:

Q. But if this condition described by Mr. Doran did not obtain, and that the conditions over there were not that way, but the conditions were otherwise, I want you to describe what would cause them to drop to that, what condition would you want to say existed to cause them to drop?—A. I won't say for any digitalis, but this sample, for any dried preparation of digitalis, I should think there should be a considerable moisture present and heat may have an effect, and there are other theories that nobody understands, but may have something to do with it.

Q. Any of the three things might happen, moisture, heat, and the next, the unknown quantity?—A. Yes.

Q. The question that the District Attorney put to you, 169 did not assume the fact that it is possible in Dr. Tagett's place, there was much heat and if so, your answer would be different?

Mr. DORAN. There wasn't any such fact. Counsel had any right in the cross-examination to bring out any of the details he thought of.

The COURT. As I recall, all the Doctor testified to was that they were kept in a closet, in a medicine chest.

MR. DORAN. And that he kept it carefully stoppered.

THE COURT. As to any other condition, I don't believe there was any question.

MR. DORAN. And I asked if kept under normal conditions.

THE COURT. I remember it was part of your hypothetical question on that. I see no objection to going into what he used as the basis for his opinions. I will receive it.

Q. Do you remember the question, Doctor, that is in answer to the hypothetical question put to you by the District Attorney, assuming that it contained the fact that there was heat, and moisture also, would that cause a drop in the potency of the drug?—A. Sufficient heat and moisture, a combination, that in fact will reduce its potency.

Q. The moisture in the hand when you open a bottle and take out the tablets, some moisture there?—A. Usually.

Q. And light is an element as you have it here in your book?—A. Yes. Do you say that is all?

Q. Just half a second, Doctor. Do you keep digitalis? You heard the expert who preceded you testify that the 170 United States Government keeps its digitalis in a refrigerator or icebox?—A. Yes.

Q. That is what you do?—A. Yes; in a locked refrigerator.

Q. It is a locked refrigerator, not an iron safe, that is also locked?—A. He said it was a refrigerator.

Q. That is the way the Government protected it, in a refrigerator?—A. According to Dr. Miller's statement.

Q. And that keeps its potency because of the refrigeration, it wasn't heat nor moisture and being properly stoppered, and it isn't the element that it is waterproof or airtight and protected from light, if you keep it in a refrigerator under a certain temperature?—A. Yes.

Q. And, therefore, it retains its strength?—A. Yes.

Q. And that is why the Government keeps it that way?—A. I believe that is the reason the Government keeps it that way.

MR. FLEISCHMAN. That is all.

MR. DORAN. That is all.

ELWOOD H. SNIDER, called as a witness on behalf of the Government, and sworn, testified as follows:

Direct examination by MR. DORAN:

Q. Mr. Snider, you are connected with what company in the city of Rochester?—A. R. J. Strasonburgh Company.

Q. What is the business of that company?—A. Manufacturers of pharmaceutical products.

Q. What is your connection with them?—A. Chief chemist.

Q. Are you a graduate chemist?—A. Yes.

171 Q. From what school?—A. The University of Rochester.

Q. What sort of chemist are you?—A. I am a general or organic chemist, specializing in pharmaceutical chemistry.

Q. What is pharmaceutical chemistry?—A. The chemistry dealing with products entering into a pharmacy.

Q. We have had some discussion here, Mr. Snider, about pills and tablets, you have heard of those terms yourself, I take it?—A. That is right.

Q. How many years experience have you had in this field you are in?—A. About 18 years.

Q. Is there any essential difference between pills and tablets?—

A. There is in their physical shape, in that one is composed of plastic material, and the other is composed of dry material.

Q. What do you mean by that, that is, that the difference is they are made by machines or what do you mean?—A. It is mainly the difference in the way they are manufactured.

Q. But otherwise, there is no essential difference, is there?—A. I wouldn't say so, from the therapeutic standpoint.

Q. Now, you know what Hinkel pills are?—A. Yes.

Q. And have been familiar with them for some years, I suppose?—A. Yes.

Q. If you get an order for Hinkel tablets, we will say, what formula would you follow for the ingredients that you use to make these Hinkel tablets?—A. Well, there is only one real Hinkel formula, and that is the one in the "N. F."

The COURT. The National Formulary?

The WITNESS. Yes.

172 Q. So when you get an order for tablets, you go to the National Formulary and find the formula for the Hinkel pills?—A. That is what I would do.

Q. And use the ingredients stated in that National Formulary, is that right?—A. Yes.

Mr. DORAN. You may ask.

Cross-examination by Mr. FLEISCHMAN:

Q. What is it, what is the formula of Hinkel pills?—A. Well, I don't recall the grains offhand. I have that here, and I can read that to you.

Q. I show you a bottle and ask you whether you know the concern whose name is on it, do you know it?—A. Yes, I do.

Q. Is that a concern here in the City of Rochester, one of repute?

Mr. DORAN. I object to that.

The COURT. Sustained. There again we have got the question of good faith.

Mr. FLEISCHMAN. No, no; just asking about the composition of the pills and tablets. I will come to that in a minute.

The COURT. What has the reputation of the firm got to do with it?

Q. What is the name on that?—**A.** J. K. Post Drug Company.

Q. That is the drug store where the Powers Hotel is?—**A.** Yes.

Q. Can you tell us what that is in your hand?

Mr. DORAN. I object to it as immaterial and irrelevant. It is a bottle which Counsel said he picked up in the J. K. Post Drug Company.

173 **Mr. FLEISCHMAN.** First, Your Honor, I want to show you that in any drug store they sell them right here in Rochester, without a prescription, and I will show another bottle from another concern and ask if that is what he means, by putting up this bottle with these requirements—

The COURT. Let us see what the question is.

The WITNESS. Will you repeat the question?

Q. Can you tell us what is in your hand?

Mr. DORAN. I object to that as immaterial.

The COURT. I will receive it.

A. The label states it is the tablet cascara compound, Hinkel, chocolate colored.

Q. Do you wish the formula?

Mr. DORAN. I object to it as immaterial, whether some other drug store supplies a pill with certain ingredients, what does that prove in this case? What bearing has that got on this question? I submit it is entirely irrelevant. If there is any question as to what the formula was at the time of this shipment, that is another point.

Mr. FLEISCHMAN. The question is as to whether a misbranding.

Mr. DORAN. You gave the inference that because some other person put out this pill under the same label, that makes it all right, and I think that is entirely irrelevant in this case. What bearing does that have on the question of whether or not the label in this case conforms to the existing formula, assuming that some other concern may have labeled it so?

The COURT. The question in this case is whether the label they used on this bottle was false and misleading.

174 **Mr. DORAN.** That is right, that is the issue. Now, assuming, we will say, that someone else puts out, a mercantile concern in pills or tablets, under the same name and we will assume the same ingredients, how does that bear upon the question, because someone else did it? I submit it is beyond the issues in this case.

Mr. FLEISCHMAN. Our contention is that if it did not contain what is on this bottle, then it would be misbranding; but the

contents are exactly what is on the bottle and, therefore, it cannot be any misbranding.

Mr. DORAN. That is a question of law.

The COURT. This is a chemist, a pharmaceutical chemist, and this is cross-examination, and I will give him some latitude. I will permit it.

A. The label states "Chocolate-colored tablets, cascara compound—Hinkel, containing: Cascara $\frac{1}{4}$ grain, aloin $\frac{1}{4}$ grain, podophyllum $\frac{1}{6}$ grain, extract of belladonna $\frac{1}{8}$ grain, strychnin sulphate $\frac{1}{60}$ grain, gingerine $\frac{1}{16}$ grain. Dose; one or two tablets at bedtime. Distributor J. K. Post Drug Company, Pharmacists, 17 Main Street, E., Rochester, New York."

Q. Is that how you would compound it?—A. I don't understand your question about compounding.

Q. You don't make pills?—A. We make our pills.

Q. If you were making them, is that what you would put in there?—A. If that is in the National Formulary, that is what we put in there.

Q. Supposing you, assuming you did, have those ingredients in there, for the purpose of not misleading the public, you would put those very things on the label?—A. Exactly, if they were in there, I put them in.

175 Q. That is a Parke-Davis product?—A. I don't know who made it.

Q. Don't you sell it?—A. I don't know who made the tablets.

Q. You don't?—A. No.

Q. I show you another, and you may open it and take it out of the case if you want. Tell us about that, where that came from.

Mr. DORAN. The same objection.

The COURT. I will receive it.

A. The label on this bottle states "Pink coated-cascara Comp. No. 3, Dr. Hinkel. Cascara $\frac{1}{4}$ grain, aloin $\frac{1}{4}$ grain, podophyl-lum $\frac{1}{16}$ grain, extract of belladonna $\frac{1}{8}$ grain, strychnin sulphate. Made for the Pain Drug Company, Rochester."

Q. They are on Main street, too, in Rochester?—A. Yes.

Q. Is there any difference between the one you just read and the one you read before as to make-up?—A. I believe one ingredient is slightly different.

Q. What is that difference?—A. On this bottle the label reads, "gingerine $\frac{1}{8}$ grain" and on the other bottle, I believe it reads "gingerine $\frac{1}{16}$ grain."

Q. What is "gingerine"?—A. That is the extract of ginger, but what the ratio is, I don't know.

Q. And the effect on the human system, no great difference, no poison, not in that bottle you have in your hand, that con-

tains the ingredients as put on the bottle, and if not exactly right, that is misbranding?

Mr. DORAN. I object to that.

The COURT. I sustain the objection to that question.

Mr. FLEISCHMAN. That is all.

176 THEODORE F. PAPPE, called as a witness on behalf of the Government, and sworn, testified as follows:

Direct examination by Mr. DORAN:

Q. Mr. Pappe, are you connected with the Food & Drug Administration?—A. I am.

Q. How long have you been?—A. I have been connected with the Food & Drug Administration and its predecessor bureau thirty-four years.

Q. You are in charge of the Buffalo station?—A. Yes.

Q. Of the Food & Drug Administration?—A. Yes; the Food & Drug Administration.

Q. Do you know of the individual defendant, Joseph Dotterweich?—A. I do.

Q. You have known him for some time?—A. Some five or six years.

Q. And you know of the corporate defendant, the Buffalo Pharmacal Company, Inc., is that right?—A. That is right.

Q. And have you in the course of your official business as between December 22, 1939, and February 20, 1940, inclusive, received letters from the Buffalo Pharmacal Company, Inc.?—A. I have.

Q. And how many of such letters?—A. There were several.

Q. And in each instance, Mr. Pappe, by whom were the letters signed on behalf of the Buffalo Pharmacal Company?—A. Signed by Joseph Dotterweich.

Q. Was there any title stated?—A. General manager.

Q. Have you there, Mr. Pappe, a letter dated on the stationery of the Buffalo Pharmacal Company, Inc., dated January 9, 1940?—A. I have, sir.

177 Mr. DORAN. Will you mark that for identification?

(Letter from Buffalo Pharmacal Company dated January 9, 1940, marked "Government's Exhibit No. 12" for identification.)

Mr. DORAN. No question but that is the signature of Mr. Dotterweich?

Mr. FLEISCHMAN. No question.

Q. That is a letter addressed to you dated at the top January 9, 1940?—A. Yes.

Q. You received it on what date?—A. On January 10th, as shown by the receiving stamp there.

Q. That is signed on behalf of the Buffalo Pharmaceutical Company, Inc., by Joseph H. Dotterweich, the general manager?—A. Yes.

MR. DORAN. I offer that portion of the letter in evidence, your Honor, which contains the title of the company on the letter-head and the date and the sender's name, the Buffalo Pharmaceutical Company, Inc., and the signature of Joseph H. Dotterweich, the general manager, which is conceded.

MR. FLEISCHMAN. No objection.

THE COURT. Received.

(Above-described portion of Government's Exhibit No. 12 for identification, received in evidence.)

MR. DORAN. That is all.

Cross-examination by MR. FLEISCHMAN:

Q. You have been connected with the Department since the promulgation of that rule which requires that you give notice to a person who is under suspicion of having done anything wrong?—A. I have been with the Food & Drug Administration for thirty-four years.

178 Q. Will you refer to your records and tell me if on or about April 15th, you wrote a letter to the corporation stating that you wanted certain information in regard to the shipments of digitalis?—A. What year?

Q. 1940.—A. Let me have my brief case, Mr. Doran. What is that date?

Q. On or about April 15th, 1940. Would you call it a form of complaint?—A. You mean a citation?

Q. That is right; a citation.—A. I can't find that. I don't find such a date.

Q. You don't find your citation?—A. Not on that date. Here is a citation of November 1939, on cascara and pituitrin.

MR. FLEISCHMAN. I move to strike it out.

THE COURT. Yes.

MR. DORAN. We can stipulate that, except possibly the date, I don't see that it makes any difference. Of course, on the admissibility of it, I don't think it is relevant in this case.

Q. Look at this one. I ask you if that is your signature on the citation?—A. Yes.

Q. On that citation that I show you?—A. Yes.

Q. Is that the citation in this case?—A. On the digitalis portion in this case?

Q. Right.—A. Yes.

Q. Who was that citation addressed to?

Mr. DORAN. I object to that. It speaks for itself.

The COURT. Well, let him read it.

Mr. DORAN. I am objecting to it being read, as it has no bearing on anything yet in this case as far as this jury is concerned.

179. Mr. FLEISCHMAN. My intention is to prove what he tried to prove by a couple of letters signed by the general manager that were not addressed to the individual, but to the corporation. Never asked Mr. Dotterweich for one thing.

Mr. DORAN. What you are leading up is the question you raised yesterday afternoon.

The COURT. He introduced a letter to show that Dotterweich was in Buffalo and signed the letter on the day it was shipped.

Mr. DORAN. That is the only purpose. I made mine over a date and a signature.

Mr. FLEISCHMAN. I want this man to identify this citation.

The COURT. Very well.

(Citation of April 15, 1940 marked "Defendant's Exhibit D" for identification.)

Q. Subsequent to April 5, 1940, on or about April 15, 1940, you wrote the letter which I now show you to the Buffalo Pharmacal Company. Is that your signature or not?—A. I wrote that letter.

Mr. FLEISCHMAN. Mark it for identification, please.

(Letter to Buffalo Pharmacal Company dated April 15, 1940, marked "Defendant's Exhibit E" for identification.)

Q. On or about April 15, 1940, did you require of the corporation here certain information with regard to a shipment of digitalis to Dr. Tagett?

Mr. DORAN. I object to it as immaterial, as far as that is concerned, and if material, it is only on the question of law.

The COURT. He may answer.

180. A. I did not.

Q. I show you a paper and ask you whether you have the original of this dated April 24, 1940?—A. I have, sir; but I didn't require it.

Q. How did it come to you?—A. Mr. Dotterweich sent it to me under the signature of the Buffalo Pharmacal Company.

Q. But this blank that you hold in your hand is on the official stationery of the United States of America, and to answer certain questions.—A. And the answering and furnishing of information in connection with that is entirely voluntarily.

Q. I didn't ask you that.—A. I said I didn't require it. I requested it.

Q. Is that upon the stationery of the Government, as used for these citations?—A. My office uses this stationery in sending out requests for information.

Q. And did you get the original of that telling you what, when and for it was purchased and all the facts in connection with it?—A. I did get the original of that paper, showing exactly what that shows.

Q. That was on April 24, 1940?—A. Correct.

Q. Do you find any error in connection with this statement in regard to what he bought, to whom he sent it and when he sent it, or anything else?

Mr. DORAN. I object to that.

The COURT. Sustained. That all goes to the question of good faith.

Mr. FLEISCHMAN. Will you mark that for identification?

(Paper dated April 24, 1940, marked "Defendant's Exhibit F" for identification.)

181 Q. Now, sir, being in charge of the Government's Food & Drug Administration in Buffalo, may I ask, does that take in Rochester also?—A. It does.

Q. Don't you know that every drug store sells, or pretty nearly every store sells Dr. Hinkel's cascara?—A. I would be surprised if they did not.

Q. And I too. I now show you these two bottles. The contents are as you have it upon this label?—A. I don't know that, Counselor.

Q. You don't know that, and that is your business?—A. With regard to one of those ingredients, I don't know.

Q. Haven't you tried to go into a drug store, laid down a quarter to get Dr. Hinkel's and got it?—A. I don't use it, and I don't get the samples that way.

Q. Is there any better way to acquire them?—A. That is one way to get it, to lay down a quarter.

Q. What other way?—A. If I want to show proof of interstate commerce at the time, we get it.

Q. Look at the one and see if that didn't come from Parke-Davis. They are in Ohio, I believe.—A. No, they are in Michigan, I think.

Q. You are right; in Detroit?—A. I don't see that it says "Parke-Davis," and of course, I don't know.

Q. It is your business to find out whether or not Dr. Hinkel's tablets are containing a substance that you say it ought not to contain, isn't that so?—A. I should say that is part of my duties in my station, but it is only one of several thousand.

Q. Tell us why did you pick upon this concern with a bottle that you can get in any drug store?—A. In the first place, you

182 say "picking upon this concern," buying the sample of this concern was entirely accidental and in the next place our inspectors cannot find a suitable official sample in any drug store, and still be sure if it did or did not move in interstate commerce, that we can prove. In the next place, if made by Parke-Davis, it is made out of my territory and not my particular immediate concern.

Q. Let me ask you this: Evidently you are concerned with the health of our citizens in your territory?—A. With the citizens in the United States in general.

Q. If you found digitalis rating lower than the amount mentioned in there, to wit: $1\frac{1}{2}$ grains, and down to $\frac{1}{2}$ of that potency, and you knew there had been a lot manufactured, why didn't you go out and pick up the rest of it in your district?—A. Mr. Fleischman, there are limits to the possibilities as to what an organization can do and we cannot do everything. We cannot do probably more than 20 per cent of what is allotted to us, with the men and the money that Congress gives us. Now, we have to try to do the work that is the most important at the moment. And I should say that would be definitely a duty that my station should perform if we knew of and could find digitalis that was only 50 per cent potent, I would say definitely that was a duty of my station to perform.

Q. Well, there came a time in 1940 when you found a bottle was sent by, or rather to Dr. Tagett, containing less than that that was required by the United States requirements?—A. Yes.

Q. And you knew that bottle came from the Buffalo-Pharmacal Company, who in turn got it from Arner & Company, you knew that?—A. Not in 1940. In fact, I didn't know until later in 1940 that the thing was sub-standard.

Q. You are on speaking terms with the other members 183 of the Government engaged in the same work?—A. Yes, that is true.

Q. In 1939, didn't you know it?—A. No; that is when it was shipped.

Q. Did you know it in 1940?—A. What is the date of that citation?

Q. That citation is April 5, 1940.—A. At that time, I knew it.

Q. Why didn't you go around and pick up all the rest, if you are dealing with poison, whether it is over or under strength, why didn't you do it?—A. I will give you the best answer that I can to it. Insofar as I am able and insofar as my organization is able, we knew just that thing you indicated there. Here is a material several months after shipment. Here is the material and whether it is possible to get any of these goods if you went out and looked for it. The next thing, in the case of

digitalis, we are definitely bound by the ability of our Washington laboratory to make the analyses, we cannot give them more samples than they can use and for that reason we have a quantity, a number of digitalis samples we are able to collect in any one year. How they are brought in to us, it is a little difficult to explain. I admit it was my duty when I found out about that, and I also admit we didn't do our duty.

Q. You had the privilege under the law, you had the privilege of coming to Buffalo, to the Buffalo Pharmacal Company and ask for a list of their customers?—A. Yes.

Q. And you never had any difficulty in getting a list of any doctors if you asked them?—A. We have had difficulty.

Q. In what way?

Mr. DORAN. I object to that, not an issue here.

184 The WITNESS. I don't want to answer a question like that one.

The COURT. Sustained.

Q. Did you have difficulty in getting a list of the Buffalo Pharmacal Company when digitalis tablets were sent in April, 1940?

Mr. DORAN. That is objected to.

Mr. FLEISCHMAN. I think it is important.

The COURT. Go ahead.

A. We never asked the Buffalo Pharmacal Company for a list of their customers or where they sent digitalis tablets.

Q. When you found on April 5, 1940, that a portion of them, that in the report of the assay, it showed a potency, less than is required by law, and you knew that is dangerous as has been pointed out, why didn't you go to that place and get a list of those customers and places?—A. I have answered that question at great length.

Q. Is that your best answer?—A. That is the best answer.

Mr. FLEISCHMAN. That is all.

Mr. DORAN. That is all.

The COURT. We will recess for five minutes.

(Short recess.)

By Mr. FLEISCHMAN:

Q. Mr. Pappe, did I understand you to say that about the time when the citation was sent out, that your department was too busy to bother about it, or something to that effect?—A. That wasn't the exact statement.

Q. I may be wrong. Give me the substance of it.

The COURT. I think we had it.

Q. As a matter of fact, did you not on May 28, 1940,
185 which was the next month, cause a seizure of the entire

product of digitalis in the Buffalo Pharmacal Company by the State of New York?—A. I had no authority to do so, but I understand that our Washington office, and which has charge of cooperation with State and City officials, did report it to the Secretary of the State Board of Pharmacy, New York, and there was present in the premises of the Buffalo Pharmacal Company a number of digitalis tablets which we found short of the potency, and which we had no jurisdiction over, because they never had moved in interstate commerce.

Q. Are you through?—A. I am, sir.

Q. Let me see if I can remind that that happened, and therefore it was quarantined?—A. I don't know.

Q. Didn't your Washington office then make an offer to notify the State of New York, and to notify the State that it was perfectly good stuff to use, and to go ahead?

Mr. DORAN. I object to that, not in evidence.

The COURT. Sustained.

Mr. FLEISCHMAN. Well, if he knows that to be a fact.

The COURT. You are trying to prove by this man who knows nothing about it.

Mr. FLEISCHMAN. I am trying to prove that he does know.

Q. Was the quarantine set upon this analysis?—A. I do not know.

Mr. DORAN. I object to that.

The COURT. Sustained.

Mr. FLEISCHMAN. Exception.

Q. Do you know after an analysis, after the analysis by the Government, the date this quarantine was lifted, if they 186 were told it was up to potency, and to go ahead?—A. I do not know.

Mr. DORAN. I object to that.

The COURT. Sustained.

Q. Do you have anything to do with the writing of this letter, or rather did you have anything to do with this letter I show you now?—A. No; I never saw it; I never knew anything about it.

Mr. FLEISCHMAN. Mark it for identification, please.

(Letter from State of New York marked "Defendant's Exhibit G" for identification.)

Mr. FLEISCHMAN. That is all.

Mr. DORAN. That is all. If your Honor please, our proof is complete, except for the introduction in evidence of a stipulation or stipulations. One of them pertains to the interstate shipment of the digitalis tablets.

Mr. FLEISCHMAN. No objection.

The COURT. Received.

Mr. DORAN. The other one, I went over one portion, and part of it contains something we are not concerned with.

(Stipulation marked "Government's Exhibit No. 13" in evidence.)

Mr. DORAN. With respect to the other stipulation, which is entitled for the purpose of identification "2104," I offer that stipulation in evidence, excepting the first paragraph thereof, that is, I am offering only the last paragraph which I mentioned, to the end or the lower portion of the second page, and from there, the balance of the stipulation.

The COURT. As I understand it, both stipulations 187 relate to only shipments of cascara compound and digitalis and shows it moved in interstate commerce.

Mr. DORAN. He has cut out the one about the date in question and it moved in interstate commerce by parcel post from Buffalo to Rock Creek, Ohio.

The COURT. The dates are not necessary.

(Second stipulation marked "Government's Exhibit Number 14" in evidence.)

Mr. DORAN. That completes the Government's proof.

Motion for directed verdict

Mr. FLEISCHMAN. If your Honor please, the defendant moves for a dismissal of the information and the charge of the individual defendant upon the ground that the Government has failed to make out a case as a matter of law, and upon the further ground there is no evidence that the condition precedent had been complied with, and no evidence beyond a reasonable doubt which would justify any matter to be submitted to this jury insofar as he is concerned, and I move for a directed verdict of acquittal, as a matter of law, as far as the individual defendant is concerned.

The Government, under the new law, has completely failed to comply with Section 335 of the Food & Drug Act in failing to give the individual defendant proper notice.

The COURT. I will let you argue on this. I will dismiss the jury for five minutes.

(Jury excused from the court room.)

Mr. FLEISCHMAN. As a matter of law, there is a reasonable doubt as to the guilt of the individual defendant under any 188 circumstances or conditions, and the arguments that were brought to your attention certainly need no repetition.

The COURT. I don't think that is a matter of law. I have one question here on this shipment of cascara compound. I will hold the motion until tomorrow morning. Bring in the jury.

(Jury returne dto the court room.)

The CLERK. The jury is excused until tomorrow morning at 10 A. M.

(Proceeding adjourned to July 2, 1941, at 10 A. M.)

Proceedings of July 2, 1941, at 10 A. M.

Present: Hon. HAROLD P. BURKE, District Court Judge.

Appearances: Same as before noted.

The COURT. Your motion of yesterday afternoon is denied, Mr. Fleischman.

Mr. FLEISCHMAN. Will your Honor grant me an exception? Have you ruled upon the other proposition?

The COURT. I will let that go to the jury.

Mr. FLEISCHMAN. Will your Honor say to the jury that this argument that your Honor ruled upon, that it deals purely with a question of law on that question, and by this denial of such motion, there is some question to the jury—

Mr. DORAN. I object to that statement, your Honor. I object to that. Let the judge caution the jury on that and we will be satisfied.

The COURT. All I will say, most of the time we have these arguments without the presence of the jury. That is what 189 we did last night, and this is merely a continuation of that argument, which was technical, and only on a question of law. I am not deciding on the facts, that is for you to do. Anything I have said here does not indicate how I feel about this case.

Mr. FLEISCHMAN. Thank you, your Honor. There are some concessions that the District Attorney wishes to make, or agreements or stipulations or what nots.

(Both attorneys approach the bench for a conference.)

Mr. FLEISCHMAN. For our purposes, I wish to renew all our motions with the same force and effect as if made today, and to your Honor's denial, I take exception.

LLOYD C. MILLER, recalled by the defendants, testified further as follows:

Direct examination by Mr. FLEISCHMAN:

Q. Dr. Miller, when you were here yesterday, when Mr. Pappe testified to some extent, as far as we were permitted to have it with regard to someone making a seizure, or a quarantine upon the digitalis that was in the possession of the Buffalo Pharmaceutical Company?—A. Yes; I heard something to that effect.

Mr. DORAN. I don't think he testified to that fact, but go ahead.

Mr. FLEISCHMAN. I don't know then that it is a fact.

190 Q. Now, will you tell me how the samples seized by the State were turned over for analysis?—A. I received a sample that purported to be collected by the State from the Arner Drug Company, and I analyzed it.

Q. Who turned that sample over to you?—A. By a Mr. Frisbee, the man in our administration, who is in charge of the cooperation between the state officials and the Federal officials.

Q. Can you answer this question, if the requirement with regard to the content or potency of digitalis is the same as with the Government?—A. I think it is, but not to my knowledge.

Q. You work in harmony with the State?—A. Mr. Frisbee takes care of it. As far as I know, it is the same.

Q. What was the date of the seizure, if you know?—A. No; I don't know.

Mr. FLEISCHMAN. Will the District Attorney concede this is the seizure made by Mr. Slade, on this date, in his handwriting upon the letterhead of the State?

Mr. DORAN. Yes; providing you will reciprocate by stipulating that those are also samples of digitalis tablets picked up on the same date.

Mr. FLEISCHMAN. If you say they are, of course, I will.

Mr. DORAN. Well, they are marked.

Mr. FLEISCHMAN. Oh, yes.

Mr. DORAN. And provided these two bottles are agreed by you or stipulated to you, to be the two samples he picked up May 28, 1940.

191 Mr. FLEISCHMAN. Is this the batch we are talking about? Mr. DORAN. Wait until I finish. I am asking you to stipulate that one bottle just marked for identification

(Bottle marked "Government's Exhibit No. 15" for identification.)

Mr. DORAN. Exhibit No. 15 for identification is the sample of digitalis tablets picked up by Mr. Slade on behalf of the State Board of Pharmacy, is that right?

The WITNESS. That is indicated on this—

Mr. DORAN. By the State Board of Pharmacy at the Buffalo Pharmacal Company at Buffalo, on May 28, 1940.

Mr. FLEISCHMAN. May 28, 1940?

The COURT. This is getting very confusing to me, and I think it must be to the jury. The issue in this case is whether a certain shipment of digitalis was under strength. Now, you are talking about some other digitalis. Now, what is the materiality of any other digitalis?

Mr. FLEISCHMAN. I can understand why you are asking that, your Honor. Let me assume this digitalis was made—

The COURT. That is just the trouble, you are assuming these things which I think should be proven.

Mr. FLEISCHMAN. They will be proven as the District Attorney knows.

The COURT. So that I understand it, do I understand that you are consenting to this order of proof to show that that digitalis came out of the same batch in question?

Mr. DORAN. Not at all.

Mr. FLEISCHMAN. I didn't know that. I thought he would concede if it came out of the same batch.

192 The COURT. That is what confuses me. If not out of the same batch, what are we talking about? How do I know or the jury know whether your digitalis they took was from the same company or the same batch, unless we have proof about it? I cannot see why we are talking about any other digitalis.

Mr. FLEISCHMAN. Do you want us to prove that we bought from this concern and no other?

The COURT. That doesn't prove anything, that would not prove it is the same digitalis.

Mr. FLEISCHMAN. I have no way of telling. I had supposed it was the same thing as that exactly. We received a notice from the Government.

Mr. WHISSEL. May I say a word?

The COURT. I don't want to clear it up in an argument. I want proof from somebody who knows. It doesn't make any difference how we argue, that doesn't take the place of proof. My point is this, I think that evidence is entirely immaterial at this stage, until you have some proof that that digitalis that you now have in your hand, came out of the same batch as the questioned digitalis.

Mr. FLEISCHMAN. I understand you. May I ask from the District Attorney a concession that this bottle I have in my hand did come from the firm that is on trial here. This digitalis which I am now showing, that is all I want.

Mr. DORAN. I just said, I would concede it came from your company and picked up there May 28, 1940, but just a moment, it has been marked for identification.

The COURT. That is the sample taken May 28th, 1940?

193 Mr. DORAN. Yes; by Mr. Slade of the State Board of Pharmacy at the Buffalo Pharmaceutical Company.

Mr. FLEISCHMAN. The letter, if your Honor please is Exhibit G, which had been offered yesterday for identification.

The COURT. What letter?

Mr. FLEISCHMAN. From the State, if your Honor please, from the State Board, Mr. Slade, at the time of the seizure. At this point then I will excuse this witness.

The COURT. All right.

(Witness excused temporarily.)

Mr. FLEISCHMAN. I am sorry, your Honor, there are so many complications, that I believe I will have to ask Mr. Miller to come back for some questions apart from this.

LLOYD C. MILLER, recalled, testified further as follows:

Mr. FLEISCHMAN:

Q. Dr. Miller, I am quoting you verbatim in your testimony of yesterday, that when you sent the samples to Dr. Chapman, it was stoppered and under refrigeration. That is your language, I believe.

Mr. DORAN. I ask to have that stricken out, the statement by Counsel, not a question.

Q. Was that your statement?—A. I don't recall that it was at all. I would like to have it read back from the stenographer.

Mr. FLEISCHMAN. It is very important that I have it read back, as there is now a suggestion that he didn't use that language.

194 **The COURT.** Whether he used it or not, that makes no difference, but it is my recollection of the testimony.

The WITNESS. I will be glad to tell you again what I did.

Q. Did you stopper it properly and it went under refrigeration?—A. No; it didn't go under refrigeration. I took this exhibit—

Q. Wait a minute.

Mr. DORAN. I object to Counsel interrupting.

Mr. FLEISCHMAN. He is not answering the question and I must interrupt.

Q. Do you want to tell this jury now that you didn't say yesterday this or this in substance: That you sent this sample from your office to Dr. Chapman, stoppered and under refrigeration. Please answer "Yes" or "No".—A. If you mean to imply—

Q. Did you or did you not say those words?

Mr. DORAN. I object to Counsel interrupting.

The COURT. I sustained the interruption. This is nothing but a continual cross-examination. You make the witness your witness and can say anything on direct, but that doesn't mean you can continue to cross-examine him.

Mr. FLEISCHMAN. I wish to say if your Honor please, if I find in the record here, and I want it clarified, that I think I have the right to ask Dr. Miller, whether it be in the form of cross-examination, as to whether he said that. That is all.

The COURT. Now, I want to say again, I am not precluding your making him a witness for any matter you want to.

195 Mr. FLEISCHMAN. All right, I will make him my witness.

Q. I say again, Dr. Miller, did you use these words, or not; Yes or No.

Mr. DORAN. Who do you think you are, to caution the witness on direct! Ask the question and let him answer it.

The COURT. Sustained, on the ground it is improper in form.

Q. Did you yesterday say, in answer to a question of the District Attorney, or in answer to a question by me, that when you sent these samples to Dr. Chapman from your office, that the sample was stoppered and under refrigeration?—A. I do not believe I did, as it is contrary to the facts, and I was under oath and trying to tell the truth.

Q. Then your answer is you did not say it?—A. I do not believe so. I don't recall that I did, and I certainly did not intend to say that.

JOSEPH H. DOTTERWEICH, defendant, sworn on his own behalf, testified as follows:

Direct examination by Mr. FLEISCHMAN:

Q. Mr. Dotterweich, where do you live?—A. In Buffalo, New York.

Q. The street and number?—A. 61 Brunswick Boulevard.

Q. How long have you been a resident of the city of Buffalo?—A. 41 years.

Q. How old a man are you?—A. 42.

Q. You were born where?—A. Dunkirk, New York.

196 Q. And you came to Buffalo when a year old?—A. My Dad died—when I was a year old.

Q. How long have you been in the drug business?—A. 23 years.

Q. That is, you were at one time connected with your brother who also has a drug house?—A. I was.

Q. About four years ago you established a business of your own?—A. It was five years ago.

Q. All right. That is a corporation?—A. Yes.

Q. And under the laws of the State of New York, it has directors and so forth?—A. Absolutely.

Q. And you make annual reports to the State?—A. Yes, sir.

Q. When you were originally, when this corporation was originally formed, what office did you hold there?—A. When it was originally formed, I was secretary, and Dr. Graser was the president.

Q. Any other officers?—A. Yes. Arthur Munn was the treasurer, and Theodore Munn, his brother, was vice president.

Q. Did you go into business at the place where you are now?—
A. Yes, sir.

Q. Do you know a concern known as Arner & Company?—A. Yes, sir; I do.

Q. Is there any connection between your firm, except as they are being wholesalers and you buy from them, in any way, do they own any stock in the corporation?—A. No, sir; they do not.

Q. Have they a financial interest in any manner, shape, or form in your business?—A. No.

Q. You buy from a great many concerns?—A. Yes, I do.
197 Q. And among the list are big concerns throughout the country; is that right?—A. Yes, sir.

Q. Do you make any drugs yourself?—A. No, sir.

Q. Will you describe to the jury just what your business is?—
A. The Buffalo Pharmacal Company is a business which purchases its medicines from such firms—am I allowed to talk in my own way?

The COURT. Until there is an objection.

The WITNESS. I am not a lawyer.

Q. Just proceed.—A. We purchase our medicines from Parke-Davis and Arner & Company—

Mr. DORAN. I don't think how they conduct their business in that respect has any relevancy.

The COURT. What is the purpose?

Mr. FLEISCHMAN. The history of the defendant here.

The COURT. What has the history to do with it? We are agreed that good faith had no part in it at all.

Q. Let us get the question of the digitalis. Do you make up any digitalis tablets or pills or any other form?

Mr. DORAN. The same objection.

The COURT. I will receive it.

Q. Do you?—A. No, we do not.

Q. There came a time, did there not, when the corporation received a notice under the law requiring you to appear before a man they proposed with regard to the digitalis?—A. The corporation received a citation on him; yes.

Q. And in response to that citation did you appear?—A. I wrote a letter to Mr. Pappe, explaining that—

Mr. DORAN. I object to that.

198 Q. You wrote him a letter; is that right?—A. Yes, I did.

Mr. FLEISCHMAN. May we have the letter, please, Mr. Doran?

Q. After you wrote him that letter, did the Buffalo Pharmacal Company get a letter requesting information?

Mr. DORAN. I object to that; no materiality to any issue in this case.

Mr. FLEISCHMAN. I am trying to prove the sequence of the evidence comes down to the question of the time when the stuff was seized by the State of New York, which is how I am getting it into evidence under the rules as they have been limited, and I am trying to do that.

Mr. DORAN. If that is the fact, what bearing would the fact whether your client sent some sort of a letter to Mr. Pappe have? I cannot see it.

Mr. FLEISCHMAN. It is my intention, my purpose, to show that we wrote to them in full as to where we got the stuff and how it was packed and everything.

Mr. DORAN. I object to the testifying.

The COURT. Assuming that you did all these things, what has that got to do with the charge of misbranding or deterioration?

Mr. FLEISCHMAN. No misbranding unless the deterioration. What I want to prove is when we shipped to Dr. Tagett it was in perfect shape from our viewpoint; and we have no way of knowing what happened there.

The COURT. I ask you, what difference does it make in view of the statute?

Mr. FLEISCHMAN. I respectfully say that it makes the difference.

199 The COURT. Are you going to attempt to prove that because you said you had no control of that, and that is the proof there was no adulteration?

Mr. FLEISCHMAN. No; I wish to prove to you, if we sent our stuff, it is perfect, and it got to a place and by reason of something being done by the individual in Ohio.

The COURT. Why not ask him where he got it? Ask him where he bought it.

Q. This digitalis that is the subject, or rather was the subject of the communication that you received from Pappe, where was it purchased?—A. From the Arner Company.

Q. When was it purchased?—A. I brought my notes with me. I can tell you approximately, I believe in December 1938.

Mr. DORAN. "I believe," that should be stricken out.

The WITNESS. Then I will show it to you. Bring me the order.

The COURT. The order, that is only an approximation.

The WITNESS. I can give you exactly, if you want the date.

Q. If I show you your original order from Arner & Company, will it refresh your recollection as to the date you gave the order?—A. Yes; it will.

Q. I show you the original order that you sent to Arner & Company.—A. This order was issued by our order clerk, Bernard Palmer, on December 22, 1938, order 3382.

Q. Did you know anything about that order when it went?—A. The order clerk automatically takes care of those things.

200 Q. The paper I show you is a paper in the regular order of business?—A. The regular order of business.

Q. And taken from your files?—A. Yes; it was.

Q. And the order is initialed by some employee?—A. The order clerk; yes.

Q. And pursuant to that order, was there an order that went to Arner & Company, 503 Michigan Avenue, Buffalo, New York?—A. Attention of Mr. Miles, for some five hundred thousand.

Q. That is half a million?—A. Yes.

Q. Half a million tablets of digitalis?—A. Yes.

Q. And when did you get the first shipment of digitalis pursuant to that order?—A. May I look at it?

Q. Will it show it to you?—A. Yes; it will. May I explain?

Q. Go right ahead.—A. This is an order of half a million tablets. The Arner Company gives—they made the whole half a million up.

Mr. DORAN. I ask that that be stricken out.

The COURT. I sustain the objection.

Mr. FLEISCHMAN. Exception.

The COURT. I am sustaining it on the ground that he testified to something that Arner does.

Q. Will you answer these questions, limited as we are, by the rules and we have to obey them?—A. I want to tell the truth—

Q. Listen to me. When did you get your first shipment pursuant to that order and what did it consist of?—A. One hundred and three thousand tablets on March 2nd.

Q. Of what year?—A. The year is not stated on here, but I do note that it is 1939 right after it.

Q. Well, approximately four months after you had given the order for it?—A. Yes.

201 Q. That is to say, you gave the order in December of 1938?—A. Yes.

Q. And your first shipment came in March 1939?—A. Yes.

Q. And subsequent to that, did you receive any further shipment, and will you tell us the dates?—A. Yes; four more shipments came in after that.

Q. And they were all for approximately one hundred and three thousand?

Mr. DORAN. Let him testify.

Mr. FLEISCHMAN. I have allowed the District Attorney—

A. The second shipment of one hundred and three thousand came in on 4-26-39. The third shipment of 112,870 came in on 6-14-39; the fourth shipment of 103,000 came in 8-9-39; and the fifth shipment of 103,000 came in 10-13-39.

Q. Now, the sale of digitalis is a comparative small part of the business?—A. Yes; only \$1.60 worth in that bottle.

Q. Did you know anything personally about the shipment made to Dr. Tagett, made to a point in Ohio?—A. No; but if you ask me to go to our file to see it was sent—

Q. Assuming that?—A. Yes.

Q. You have no reason to dispute it?—A. No reason to dispute it.

Q. Prior to yesterday when Dr. Tagett took the stand, had you met the gentleman?—A. I have never seen him before.

Q. With how many doctors do you deal in your business?—A. We have around ten thousand.

Q. As you get orders in, you file them?—A. Yes; and, of course, we fill them as well.

202 Q. Your company fills the orders through its shipping clerk, or whoever it is?—A. Yes.

Q. Tell us something as to how that is done in the business.—

A. The company is almost automatic in its operation. I worked very hard in establishing that in the company and it dragged my health down—

Q. Listen—A. I want to tell you.

Q. What part of the work is yours particularly?—A. I do so little now that I leave Mr. Munn in charge.

Mr. DORAN. That is objected to, if the Court please.

The COURT. Strike it out.

Mr. FLEISCHMAN. We consent.

Q. What do you do now?

Mr. DORAN. I object to that.

Q. What did you do on the date when you sent out that order to Dr. Tagett in Ohio?—A. I don't know of any town.

Q. Have you any recollection of this deal with Dr. Tagett at all?—A. No; I wouldn't remember that at all.

Q. When did you for the first time hear of anything in regard to the sale made to Dr. Tagett of the tablets?—A. When Mr. Pappe sends in the citation to me.

Q. After that citation was sent in to you, what did you do with reference to your digitalis?

Mr. DORAN. I object; if the Court please.

The COURT. Well, now, you are talking about some other digitalis.

Mr. FLEISCHMAN. No; about this very digitalis I am trying to explain when it was made up—

The COURT. I know that, but I say what you say doesn't make any difference and not what I say. The only way you 203 can prove that is by somebody who knows something about it, and you don't know nor I don't know.

Q. After you got this digitalis, this one hundred and three thousand or a million or half a million of the stuff, did there come a time when the State of New York quarantined your digitalis?—A. Yes.

Mr. DORAN. That is objected to.

The COURT. Sustained.

Mr. FLEISCHMAN. I respectfully take exception for the purpose of record, and may I continue with one more question in that same line?

The COURT. Very well.

Q. Was that digitalis which the State quarantined a part of the shipment of a half million tablets of digitalis, out of which Dr. Tagett received a shipment?—A. Yes.

Mr. DORAN. I object to that.

The COURT. I will receive it.

Q. After it was quarantined by the State, tell us what you understand by a quarantine in the drug business.—A. Mr. Slade came in and he said that he was going to seize and quarantine the digitalis stock, and he sealed it up with the State seal.

Mr. DORAN. I submit that this is not the way to prove it.

Mr. FLEISCHMAN. He conceded the fact that Slade grabbed this stuff, and that is what happened.

The COURT. In spite of the fact that he conceded it, what difference does it make unless it is the same digitalis? Will you come to the stand a minute, please. Mr. Fleischman, if somebody and not you, if it is the fact they can say that this 204 questioned digitalis came out of the same batch as some other digitalis of which you had an analysis, and I don't know who it is, but you cannot testify to that.

ARTHUR J. MEIER, called as a witness on behalf of the defendant, and sworn, testified as follows:

Direct examination by Mr. FLEISCHMAN:

Q. Your address?—A. My home address is 72 Parkside, Buffalo.

Q. Tell me what is your business.—A. I am vice-president and general manager of the Arner Company, Inc., 303 Michigan Avenue, Buffalo.

Q. And that company is engaged in what business?—A. Manufacturers of private formulas, specialties in pharmaceuticals exclusively.

Q. How long have they been in that business?—A. About thirty-five years.

Q. And has the Arner Company in any manner, shape or form, any interest in the concern known as the Buffalo Pharmacal Company, either by an investment in its capital, the ownership of its stock or in any other way, except to sell them material?—A. No.

Q. Are you in active charge of that business, Mr. Meier?—A. Yes, sir.

Q. By the way, am I correct in saying that you are one of the largest pill houses in the world?

Mr. DORAN. I object to that.

The COURT. I will receive it.

A. We are the largest private manufacturers in the world. You understand that the other concerns he mentioned in 205. this court make preparations of their own and larger than we are in capital stock, but we are the only concern of its kind that makes pharmaceuticals for others. We make no product under our label, and in that way, we are the largest concern of the kind.

Q. I gather from that that you get orders from people to manufacture whatever they want and that is what you do?—A. Yes, we have it from individuals and serve other pharmaceutical houses.

Q. In the thirty-five years of business, have you ever had any trouble in reference to the products of your business?

Mr. DORAN. That is objected to.

The COURT. Sustained.

Q. Now, I show you an order purporting to be a purchase order from the Buffalo Pharmacal Company to your concern for half a million digitalis tablets.—A. Do you mind if I compare with my own notes?

Q. Not at all.—A. Yes, sir.

Q. You came here under subpoena from the District Attorney, did you?—A. Yes.

Q. I never subpoenaed you to come here?—A. No.

Q. I ask you if you came here after I phoned you?—A. Yes.

Q. Did you at that time bring your books and papers in pursuant to the subpoena?—A. I brought what Mr. Doran requested.

Q. And you submitted them to Mr. Doran?—A. Yes.

Q. And after he looked at them, he excused you and told you to go home?—A. Yes.

Q. He paid you of course?—A. He did.

Q. Referring to this order of five hundred thousand digitalis tablets, will you tell me what grain was ordered
206 by this order?—A. One and one-half grain of digitalis, U. S. P. unit.

Q. When you got this order will you tell the jury what you did?—A. When we received the order, we from our supply ordered the necessary bottles and digitalis to make up half a million tablets. We made more than a half a million, it was five hundred and twenty-five thousand, as we write all our manufacturing cards five per cent in excess of the order, allowing for loss and so forth.

Q. Where did you order it?—A. We ordered the digitalis from S. E. Penick and Company.

Q. Who are they?—A. We consider them one of the largest and most reliable of the importers of drugs and this drug.

Q. In pursuant to that order, you got the drug?—A. Yes, powdered.

Q. Then you proceeded to do what with it?—A. We proceeded to make the tablets as we usually make.

Q. Will you tell me what you do in a very general way?—A. Well, of course, we order the material. The material is received by us from our supplier, who is S. S. Penick & Company, as I said before. It comes to our receiving room, and a sample is sent to the control laboratory for identification. Then it goes to the custody of our pharmacy department. Manufacturing cards are written for this formula. They go to the pharmacy department and the materials are assembled for granulation and they are compressed into tablets.

Q. When you say they are granulated, what do you mean by that?—A. I mean by that we get the material with the proper diluent. This called for a one and one-half grain tablet. 207 The finished tablet is supposed to weigh three grains. We add enough material to bring up to the weight it should be. This is made in accordance with a sample submitted by the Buffalo Pharmacal Company, so we had a reproduction to use and a weight to make.

Q. When you got through, did you have a tablet, the content of which was one and one-half grains of digitalis?—A. We did.

Mr. DORAN. I object to that and ask to strike it out.

The WITNESS. Well, by weight we did.

The COURT. What is the question?

Mr. FLEISCHMAN. Did you have a one and one-half grain tablet?

The WITNESS. We had a three-grain tablet with one and one-half grains of digitalis in it.

Mr. FLEISCHMAN. But the content of that was one and one-half grains digitalis.

Mr. DORAN. Well, of course, I don't know whether he knows.

The COURT. There isn't any question on the weight!

Mr. FLEISCHMAN. No. Just talking about the digitalis potency.

The COURT. Your question did not embrace that. You said, "Did the pill weigh one and one-half grains?" That has to do with the weight of it, and not the strength.

Q. The weight of the tablet is three grains?—**A.** That is the final tablet.

Q. How much of the three-grain tablet is there in digitalis?—

A. One and one-half grains.

208 **Mr. DORAN.** I object to it unless we know the basis of it, and I ask to have it stricken out.

The COURT. Well, I take it the only person who can testify on the potency, if that it what this embraces, is somebody that made a test of it.

Q. Are you a chemist?—**A.** Yes.

Q. And you made these tests at all times upon this digitalis?—
A. What is the question?

Q. How many digitalis tablets have you made in your lifetime? A million, haven't you?—**A.** That is a hard question to answer.

Q. Well, approximately, give us your best judgment.—**A.** I don't know. There are a lot of clients in thirty-five years. It probably exceeds that.

Q. You are a chemist?—**A.** A pharmaceutical chemist.

Q. And you know what you are making up, the pill, what the content of it is?—**A.** Absolutely.

Q. Do you know what the compound is that goes into digitalis, a foxglove leaf compound?—**A.** Yes.

Q. That is what you put into these pills—**A.** Yes.

Q. Do you yourself make the tests?—**A.** No.

Q. Who did in this case?—**A.** Our control laboratory.

Q. Is your chemist here?—**A.** He is not.

The COURT. I am sorry, Mr. Fleischman, but these are important matters, and it is the very gist of this whole case. We must have the testimony of someone that knows about it. The president is not supposed to know about it, except in a general way.

The WITNESS. If your Honor please, may I address the Court? I think what Mr. Fleischman is trying to prove is that these tablets had one and one-half grains digitalis and that is all I am trying to testify to. I testified that I knew they did.

209 **Mr. DORAN.** I ask to strike it out.
The COURT. Strike it out.

Q. How do you know?

Mr. DORAN. I object.

A. By consulting records of the finished stock.

Mr. DORAN. I object to that, because the witness concededly did not make the tests. He just said he didn't. We have got to abide by the rules of evidence here, and I submit there is a proper method of proof. It cannot be waived. It is not a matter of convenience or courtesy, it is a matter of proof and I object to it.

The COURT. This is the whole gist of the matter. You are trying to show that the whole batch was right. You have to show that by someone who knows about it, who made it.

Mr. FLEISCHMAN. This is a chemist and under his direction, with thirty-five years experience making it. Perhaps the next question will qualify it.

Q. Did you ever, in making the tablets, have anyone find fault with them?

Mr. DORAN. I object to that.

The COURT. Sustained.

Mr. FLEISCHMAN. My position, we will have to get this chemist up here. Is that what your understand?

The COURT. Not what I understand, it is the rules of evidence. If you are going to prove the content of a certain article, you cannot prove it by the president of the company. He might testify generally what they did, and that was all done under supervision, but when you get to the point of some pills, you have to have the man that analyzed it. No deviation from that, it is as plain as A, B, C.

210 **Q.** In your trade, who is the one that make or analyzes the product of your company?—**A.** It goes through different department heads. They are responsible for it, and shown on the manufacturing cards.

Q. Who is the chemist in charge, if there be any?—**A.** Our chief chemist is Roy Clark with three assistants.

Q. Is he the man under whose direction this is done, he makes the test?—**A.** Not necessarily.

Q. Who would it be?—**A.** The foreman of the pharmacy department, but he makes no test on the potency. He makes one on the manufacturing and production to see that he gets the proper mixture and the right amount in the tablets as pressed out, and we judge our return by the yield that we get.

Q. What is that "by the yield"?—**A.** I can tell you from notes, if you will allow me. I have all the dates.

The COURT. When it left your plant was any test of the potency made?

The WITNESS. No.

The COURT. That is what you are trying to demonstrate?

The WITNESS. No potency test made, but an actual check made by weight.

Q. When it left your plant was there anything submitted by you to the Government of the United States of that batch that left your plant?—A. No.

Q. Did they come at any time and take of that batch any test?—A. No.

The COURT. Well, in view of that, I do not think that the United States Attorney raised any question on the weight.

Mr. DORAN. No; only the potency and the strength.

211 The COURT. And this man could testify to the weight?

Mr. FLEISCHMAN. That doesn't do me the slightest bit of good.

Q. Of that batch, was there any analysis made by the Government at all?—A. No.

Q. Did you sell any of that product, whatever it contained, whether it contained heifer dust or anything, did you sell any of it?—A. Only to the Buffalo Pharmacal Company.

Q. Did you sell the entire product that you made to the Buffalo Pharmacal Company?—A. Yes.

Q. And in what shipment did you give to the Buffalo Pharmacal Company?—A. There were five shipments.

Q. Did you add or take anything away from what was made at the time that you sold to the Buffalo Pharmacal Company?—A. No.

Q. That is the stuff that the Buffalo Pharmacal Company got in your shipment of one hundred and three thousand at the time approximately?—A. Yes.

Q. Did you hear that subsequently there was part of that product taken away for examination by the Government of the United States?—A. Yes.

Q. Well, now, whatever shipments you made of the one hundred and three thousand, one hundred and three thousand, one hundred and two thousand, and again one hundred and three thousand of that stuff, was that stuff the same granulation of the same make at the time you made up the five hundred thousand pursuant to this order?—A. Yes.

Q. Do you have a control number?—A. Yes.

212 Q. Well now, I have got to have from you what the control number is.—A. It is the formula number under which it is manufactured.

Q. Now, was that a part of this batch or mass of granulation that we are talking about?—A. Yes.

Q. Did that go to the Government of the United States?—A. No.

Q. Where did it go to?—A. The Buffalo Pharmacal Company.

Q. To the Buffalo Pharmacal?—A. Repeat your question. I—yes; they got all the finished product.

Q. Was there any retained by you?—A. Certainly, the control sample.

Q. What became of this control sample, that is what I want?—A. That was sent the latter part of May or the first of June to S. E. Penick & Company for analysis.

Q. This control sample that you sent to S. E. Penick, was report of that made?—A. Lot number one.

Q. There wasn't any other that went into this control sample?—A. No.

Q. Did you sent that to S. E. Penick?—A. Yes.

The COURT. In May?

The WITNESS. The latter part of May or the first part of June.

The COURT. What year?

The WITNESS. 1939, that would be.

Q. Have you got the date there?—A. I think I have it here. No, it was sent in 1940, I beg your pardon, it was sent in 1940.

Q. Was that sent at the time that the Buffalo Pharmacal Company communicated to you the fact that they had received some kind of a citation?—A. It was not sent on the exact day.

213 Q. Approximately.—A. It was around that time, a week or so later.

Q. But what you sent to them, a report was made of that, did you know, by Dr. Chapman?—A. Yes.

Q. You know of your own knowledge that Dr. Chapman reported that it complied with every requirement of the Government?

Mr. DORAN. Don't prove it that way.

Q. Was that part of the same memo?—A. Yes.

Q. Is there any left over in your possession now?—A. No.

Q. What is now left over?—A. Well, our control samples of necessity are not large. Perhaps between forty and fifty tablets. And at the time these tablets were sent, that is, of this lot, to whomever made the test we sent the entire samples.

Q. Try to get this picture clear: Whenever you made up samples for control, the samples are sent to the Buffalo Pharmacal Company?—A. To the Buffalo Pharmacal Company.

Q. You keep only for yourself the sample?—A. Yes.

Q. When you sent this sample to Penick & Company, then you were free to tell that you had no more of that stuff?—A. We had no more.

Q. How long have you been in the manufacturing, you say for thirty-five years, of pills and tablets?—A. The Arner Company, yes.

Q. Will you please tell us, is there a difference between pills and tablets?—A. Sure there is.

Q. And you ought to know that, if a manufacturing chemist of thirty-five years' experience.—A. Yes.

Q. Will you tell us in detail what is the difference between 214 pills and tablets, except its physical make-up, I care nothing about that.—A. A tablet is pressed from a dry granulation or powder, and the pill is made by two distinct processes: The first is what we term the mass method, and the second is the pulverizing method. The pills in the mass method are made up by properly mixing the ingredients in machines until they are of the consistency of heavy putty, or stiff dough. Then they are in the automatic tablet machines and made into pills, either round or oval. This mass in the finished pill contains anywhere from ten to twenty percent of moisture. When the pills come from the machine they are cured by drying either air-dried or in the controlled kiln. Then they are ready to market to the customers of our company. If they are required to be coated, then, of course, they are coated. It is a much costlier process in making the pills than the tablets. There is a difference between them from the manufacturer's and customer's standpoint.

Q. Do you know that the United States Pharmacopeia talks about pills?—A. And tablets.

Q. The pill is one thing and the tablet is another, that is your experience in thirty-five years of business?—A. Yes.

Mr. FLEISCHMAN. That is all. You may ask.

Cross-examination by Mr. DORAN:

Q. You mean that the difference is in the making of them?—A. It is the procedure in manufacturing. For your information the pill is more costlier to make, and tablets are the outgrowth of pills.

Q. The tablets, I suppose, that is the machine age of pills?—A. Yes; it is the machine age of pills.

Q. Mr. Meier, in making up these digitalis tablets for 215 the Buffalo Pharmacal Company that we are talking about, did your company use a preparation of those tablets what is known as the excipient?—A. Yes.

Q. What is the excipient?—A. The excipient we term it is an inert ingredient. Common sugar is one. Salt may be another. Starch may be another.

Q. That is, I take it, that some other ingredient or inert material that you mix in with your drug to bind?—A. To build up and to bind.

Q. To build up and to bind the tablets together?—A. Correct. Q. And those you mentioned are some of the excipients, are they?—A. That is right.

Q. Tell us, if you will, Mr. Meier, what excipient was used in this batch of tablets that was made for the Buffalo Pharmacal Company?—A. Cornstarch and sugar. The liquid we used for the granulation was 20 per cent gelatin.

Q. Do I understand you correctly from your testimony, that this whole batch was made at one time?—A. At one time.

Q. So that the one batch, the amount of excipient was put into that batch?—A. At the same time. It was not divided. You see I have looked up the record. There were two hundred fifteen pounds and some ounces in this batch. We are built for production and have machines large enough to handle the entire amount at one time.

Q. So that there would be uniformity in your excipients throughout the tablets?—A. Oh, yes.

Q. Mr. Meier, Mr. Fleischman asked you about a sample that was sent to Penick & Company and you said that was in 216 June, 1940.—A. It was just prior to the date of Dr. Chapman's report, probably taking a day or a night to get to New York City and another day or two to get to Chapman, either the latter part of May or the first week of June. I don't just recall that date. That particular transaction was carried on over the telephone. We got in touch with Dr. Lewis of Penick for someone to make the tests for us. He recommended Dr. Chapman and said, "If you will send the sample to me, I will send it on to him."

Q. Do you remember just before that there was another sample picked up by Mr. Slade?—A. Yes, I was present and gave him that sample personally.

Q. Mr. Slade was connected with the New York Board of Pharmacy?—A. Yes, and he properly identified himself.

Mr. DORAN. Will you mark that for identification?
(Bottle of pills marked "Government's Exhibit Number 16" for identification.)

Q. The tablets in that bottle came from the same batch?—A. No, sir; not from the same batch. That was a subsequent batch. We had no tablets when Slade came in. Our record shows we

made all our shipments to Dotterweich. We had both from batch number one and when Slade came. That is batch number two.

Q. Not the same batch?—A. No.

Q. This other sample that you sent to Penick & Company?—A. That was our control sample of the first lot. I testified to that. That is all we had at the time.

The COURT. This Exhibit 16, when was that picked up?

The WITNESS. He picked it up May 15 or something, it is dated.

217. Mr. DORAN. May 28th, is that right?

The WITNESS. That is better.

The COURT. May 28th, 1940?

Mr. DORAN. Yes.

The COURT. At the time you had sent the control sample to Penick?

The WITNESS. In the first lot, not the second lot. The second lot was what the State picked up.

The COURT. When you speak of batch number two, that is what you made for someone else?

The WITNESS. No; for the Buffalo Pharmaceutical Company on the later order we received subsequent to the first order.

The COURT. I see.

Mr. DORAN. That hadn't been shipped yet, that second one?

The WITNESS. I cannot tell without the record.

Mr. FLEISCHMAN. I assume the second shipment has nothing to do with this case. I know nothing about it. We are concerned just with the one to Dr. Tagett.

Mr. DORAN. Well, I don't know. He knows the fact. That is all.

Redirect examination by Mr. FLEISCHMAN:

Q. Now, I show you a report and ask you if that is the report that you got on the Penick shipment of the sample that you had?—A. Yes.

Mr. FLEISCHMAN. We offer it in evidence.

Mr. DORAN. Oh, no.

Mr. FLEISCHMAN. It is an official document by the Doctor. He said that is what he reported.

218. The COURT. I believe the Doctor testified yesterday that was 0.78.

Mr. DORAN. Yes.

Mr. FLEISCHMAN. I want to read it.

Mr. DORAN. He already testified to it.

The COURT. I think it is now admissible.

Mr. DORAN. All right.

(Defendant's Exhibit "C" for identification received in evidence.)

(Mr. Fleischman reads Exhibit to the Jury.)

Re-cross-examination by Mr. DORAN:

Q. So there won't be any misunderstanding in my mind, if we ask a question or two of Mr. Meier: these five hundred thousand tablets that you speak of, Mr. Meier, let us see if we understand each other correctly on it. You made them up in one batch!—
A. One batch.

Q. This second batch that you just mentioned a moment ago, that had nothing to do with the five hundred thousand tablets at all?—A. Made at an entirely different time.

Q. And these five hundred thousand tablets you speak of were shipped on those dates?—A. The same dates—I have a certified copy.

Q. Are they the same dates?—A. The same dates as Mr. Dotterweich, and the same dates as your court records show.

Mr. DORAN. That is all.

Redirect examination by Mr. FLEISCHMAN:

Q. May I add to this: When was the first shipment of batch number two made, have you any idea?—A. No.

Q. If you got the order in 1940, it was sometime prior to that time?—A. You see a discrepancy on dates from 219 the time the order was received and afterwards, but they are in advance of the requirements and we schedule all our production schedules as we make them. These tablets were made and compressed and ready for delivery within three days after we started.

Q. If we sent tablets to Dr. Tagett January 8, 1940, that must have been from the first batch?

Mr. DORAN. Don't try to prove from this witness what Mr. Dotterweich did.

The WITNESS. That would be Mr. Dotterweich.

Mr. FLEISCHMAN. All right. Thank you.

JOSEPH H. DOTTERWEICH, recalled, testified further as follows:

Direct examination by Mr. FLEISCHMAN (continued):

Q. Now, Mr. Dotterweich, you got the first shipment from the Arner Company or the first batch in the five shipments that you have testified to?—A. Yes, sir.

Q. Now, the stuff that was on January 8, 1940, assuming that was January 8, 1940 which was testified here by your man and admitted by us, there was sent to Dr. Tagett one thousand tablets. What shipment was that from?

Mr. DORAN. I object to that. I don't know that he knows about that or not.

Q. On January 8, 1940; had you received any part of the second batch?—A. I wouldn't remember.

Q. Is there any way of looking that up?—A. No, sir; I wouldn't be able to unless I went into the records.

Q. And if you went into the records, you would know when that second batch was received?—A. Yes.

220 Q. Now, sir, during that period of time, did you buy any digitalis tablets from any other concern?—A. No, sir.

Q. Now, coming back farther to the time when Mr. Slade came into your place, and as you say, quarantined the digitalis, did he leave with you at that time, a letter as to what he was doing?—A. Yes, sir; he did.

Q. I show you a letter which is marked "Defendant's Exhibit G" for identification, and I ask you if that is the one he left?—A. Yes; I recognize it right away.

Mr. FLEISCHMAN. We offer it in evidence.

Mr. DORAN. Well, go ahead and connect it up. Lay your foundation for making your offer.

Q. After this letter was left with you which was in the form of a receipt, let us say, for what he quarantined or took, he took a sample?—A. Yes, sir.

Q. You don't know what became of that sample to your own knowledge?—A. You mean after he took it?

Q. Yes.—A. No; I don't know.

Q. Did there come a time you got a telephone call from the State Department saying "We found it O. K., go ahead with this"?

Mr. DORAN. I object to that.

The COURT. Sustained.

Mr. FLEISCHMAN. I thought it was conceded.

The COURT. No; you are talking about digitalis. I don't know, nor the jury doesn't know if batch number one or not.

Q. The digitalis that was taken by Slade, was that the first batch of digitalis?—A. Yes, sir; it was.

Q. Now, sir, the sample they took from your place was from the first batch of digitalis that you received from Arner & Company?—A. Yes, sir.

221 Q. Now then, after they had taken it how long was it before you heard from anyone in Albany or Washington or anyone else?—A. If you give me the date from the record, if you want to say within a few weeks; within a few weeks; the New York State Bureau of Pharmacy called me on the phone.

The COURT. Just a moment. I take it you now have the sample identified from batch number one.

Mr. DORAN. I have no objection to it going in evidence now.

The COURT. That is Exhibit 15 for identification.

Mr. FLEISCHMAN. I don't even what it is about.

The COURT. That is Exhibit 15, the sample that Slade took on May 28th?

Mr. DORAN. Yes; from the first batch.

Q. Then you received word from the State of New York from Mr. Slade?—A. Not from Mr. Slade.

Q. Who from?—A. I believe Mr. Mather who is the secretary of the New York State Board of Pharmacy. He telephoned me and said the tablets were O. K.

Mr. DORAN. I object to that.

The COURT. That doesn't make the analysis result O. K. by calling on the phone and saying "O. K."

Q. Did you subsequently have that quarantine lifted?

Mr. DORAN. I object to that.

The COURT. Sustained. I am not precluding you showing what the analysis of the sample was, but not saying that over the telephone, that is only an inference somebody made on the analysis, but the important thing is the analysis itself.

222 The WITNESS. May I assure you that—

The COURT. You have a lawyer here that I assure you is not missing anything at all.

The WITNESS. I would like to tell what they told.

Q. You tell us what took place.

Mr. DORAN. No, no.

The WITNESS. Why do you object to me telling the truth?

Mr. DORAN. I told your Counsel last night who made the analysis, I was there and you were there, when I told him.

The WITNESS. That doesn't stop me from telling the truth.

Q. Mr. Dotterweich, did you continue to so sell digitalis from that batch after that?—A. Yes.

Mr. DORAN. I object to that.

The COURT. Sustained.

Mr. FLEISCHMAN. Exception.

Q. Pills from that batch had gone, as far as you know, a package to Dr. Tagett before that time, before the State stepped in; the Tagett stuff, so far as you know, had been sent?—A. Yes, sir.

Mr. DORAN. This Exhibit 15, the sample picked up by the State on May 28, 1940, that the witness said was from the first batch, that is offered in evidence.

The COURT. Received.

(Government's Exhibit Number 15, for identification, received in evidence.)

Mr. FLEISCHMAN. Did you hear anything more from Pappe or the State of New York, or anything with reference to that?

223 Mr. DORAN. I object to that.

The COURT. I will receive it.

The WITNESS. No, sir; we did not.

Mr. FLEISCHMAN. That is all. You may examine.

The COURT. We will recess for five minutes.

(Short recess.)

Cross-examination by Mr. DORAN:

Q. Mr. Dotterweich, I just want to ask you a few questions and it won't be many. Mr. Munn, who testified yesterday, Arthur Munn, he is your brother-in-law?—A. Yes, sir; he is my brother-in-law.

Q. You heard him testify his part in the business?—A. Yes, sir; I did.

Q. And you agree that you were, during October 1939 and in January 1940, the general manager of this Buffalo Pharmacal Company, Inc.?—A. Yes, sir.

Q. No question about that, is there, and as a matter of fact you were in charge of all of the operations of the company during those months, were you not?—A. I don't know just—

Q. You supervised then and you were the boss?—A. I was the boss, yes, and I don't dodge that for a minute; I don't dodge that for a minute, I was the boss, but, sir, I was in and out often.

Q. But the employees that worked for your company during those months of October 1939 and January 1940 worked under you, didn't they? Under your direction? You were the boss, weren't you?—A. Yes, sir.

Q. There was no other boss there as a matter of fact?—A. I am in and out very much, and when I am out somebody must be the boss.

224 Q. You mean out of town, is that it?—A. Yes; and other times even when I am in town, I am not at work, and somebody must be the boss; you don't leave 27 people without somebody in charge.

Q. But when you are in town, you are the boss?—A. Supposing I don't come to work until ten in the morning, for some reason, and the employees start at 8:30, who they do respect as the boss is Mr. Munn.

Q. Do you want the jury to understand that somebody else is also a boss there? I want the fact.—A. When I am away, Mr. Munn is the boss, and when I am in the place, I am in charge.

Q. That is right?—A. That is the truth.

Q. So that on the day, we will say, when you were there, and wrote a letter, you were the boss, weren't you?—A. There were not many letters.

Q. Do you want us to understand that in the business day when you wrote a letter out of that company as its general manager, that someone else was the boss, do you want to fix the responsibility on somebody else?—A. No; I don't want to dodge it one bit.

Q. Were you the boss on the ordinary business day when a letter was written out under your signature?—A. Yes.

Mr. DORAN. That is all.

Redirect examination by Mr. FLEISCHMAN:

Q. If you were out to lunch, who is the boss?—A. Mr. Munn.

Q. And if you are away a half day, who is the boss?—A. Mr. Munn, and it is right on the bulletin board for many years.

Q. You are assuming any responsibility in connection 225 with the business as general manager, except the times that you were away; is that right?—A. Yes, sir.

Q. Let me ask you for instance in connection with your business, let us take a typical day when the orders come in; do you fill them?—A. I don't even see them.

Q. You never even see them?—A. No.

Q. Who does see them?—A. The girl from the office goes to the post office and brings the mail to the office, and they grab it before I get there and that is at 8:30.

Q. If orders from doctors, tell us what happens.—A. The girl opens the orders and passes them on to others. They check and invoice them and then pass on to another girl who fills the order from the stock shelves, and then they pass into the shipping department people who handle the packing and shipping of them.

Q. What is your job, what part of the game?—A. General overseeing. I have trained people to handle that. I couldn't do all these things, it wouldn't be possible, it is utterly impossible for one man to do such a thing.

Mr. FLEISCHMAN. All right.

Re-cross-examination by Mr. DORAN:

Q. That is just it, I don't mean to say you do all of these things, but who ever does it, you are the boss, and they do it under your supervision?—A. When I am there.

Q. Are you the general manager of this company?—A. Yes.

Q. Do these girls that you just talked about, with Mr. Fleischman, are you their boss; do they work under you?—A. Yes.

226 The WITNESS. I can give you an example.

The COURT. You are the boss too when you are not there?

Mr. FLEISCHMAN. You are the general manager of the concern if not there?

The WITNESS. Sure. The employees complain when I am away, because Mr. Munn, who is the boss, is strict with them.

Mr. FLEISCHMAN. You are too easy.

The WITNESS. I must be, I guess.

Mr. FLEISCHMAN. All right.

Mr. DORAN. You don't appoint him as general manager when you go out to lunch?

The WITNESS. That seems ridiculous.

Mr. DORAN. I want to know. You are still the general manager of the company when you go out to lunch?

The WITNESS. Yes, sir.

Mr. DORAN. All right.

Mr. FLEISCHMAN. That is all.

ARTHUR J. MEIER, recalled, testified further as follows:

Re-cross-examination by **Mr. DORAN**:

Q. Probably I didn't ask you, but I would like to ask you this question: This first batch of five hundred thousand tablets that you testified about that were made for the Buffalo Pharmaceutical Company, when was the manufacture of these tablets completed?—A. The manufacturing or processing was started 1-25-39 and finished 2-3-39, that is, February 3, 1939.

227 Q. The whole batch?—A. The whole batch all at once.

Q. Now, as I understand it, do you air-dry these tablets?—A. Yes, sir.

Q. Is the purpose of that to protect these tablets from normal heat in the future?—A. Yes; and the presence of moisture.

Q. In your opinion it does?—A. When we manufacture them, if we subject them to a high temperature—and the presence of heat and moisture is destructive to the active principles of digitalis—we don't subject digitalis where the potency is destroyed by heat, we don't subject to kiln heat, it is air-dried with a temperature of about 85-90 degrees Fahrenheit.

Q. The purpose is to protect them from normal heat in the near future?—A. Yes.

Q. And in your opinion it does?—A. Yes.

Mr. DORAN. That is all.

Redirect examination by **Mr. FLEISCHMAN**:

Q. In your opinion, what does cause deterioration, if anything other than time causes it?—A. Well, just what the Pharmacopeia calls for in preserving of it. The digitalis is just as susceptible as the uncoated drug.

Q. Well, light will affect it?—A. Yes.
Q. Heat will affect it?—A. Yes.
Q. Moisture will, of course, affect it?—A. Yes.
Q. And if a pill is put in the hand and then put back in the bottle, there is moisture there in the hand?—A. Yes.

Q. And that will affect it?—A. Yes.
Q. You don't handle them by hand in your place. By the way, do you know what the water content of these tablets is?—A. 4½ percent.

Q. And the United States Pharmacopeia permits 5 percent?—A. Yes.

228 Q. You are lower?—A. There is a loss of water in the process of drying.

Q. Can you give us any idea, as a chemist, as to what the moisture in the hand would be, the ordinary moisture is all I can ask you on that.—A. I couldn't tell you that.

Q. There is moisture, though?—A. Yes.
Q. So you will agree with Dr. Chapman?—A. I agree with anything that he said; anything that Dr. Chapman said.

Mr. FLEISCHMAN. That is all. That is all, your Honor.
The COURT. Is the evidence closed?

Mr. DORAN. I have one witness in rebuttal.

The COURT. All right. We will take him now.

GEORGE L. KEENAN, called as a witness on behalf of the Government, in rebuttal, and sworn, testified as follows:

Direct examination by Mr. DORAN:

Q. Mr. Keenan, you are employed by the Food & Drug Administration?—A. I am.

Q. How long have you been?—A. Since January 1913.
Q. And in what way are you connected with the Food & Drug Administration?—A. A microanalyst for the Food & Drug Administration.

Q. What is that?—A. The duties of a microanalyst consist of the microscopical examination of foods and drugs, of miscellaneous samples.

Q. You mean by that you examine them under a microscope?—A. I examine them under the microscope.

Q. For what purpose?—A. For the purpose of deviating their constituent ingredients and comparing their general identity with other materials.

Q. I fancy that is the Food & Drug Administration in what is called the microanalytical division?—A. I am a member of the Microanalytical Division.

Q. That is a different type of an examination, I take it, from the biological assay or test and so on?—A. It is purely microscopic.

Q. Have you some education along that line, Mr. Keenan?—A. I got my undergraduate work at the University of Michigan, and also my graduate work.

Q. In what?—A. In the general field of microscopy, biology, and related subjects.

Q. You specialized in microscopic examinations?—A. Yes.

Q. That is what your branch of your education was?—A. That was my specialization.

Q. Did you graduate from there?—A. I did.

Q. Did you get a degree?—A. I got a degree of Bachelor of Science, and Master of Arts, from the University of Michigan.

Q. That pretty well covers your education?—A. I also had post-graduate work in the Graduate School of the Department of Agriculture, Washington, D. C.

Q. In what line?—A. Analytical crystallography.

Q. Is that in the same field with the microanalyst?—A. A microscope is required in that field.

Q. In other words, it is further education along the same line of work?—A. That is it.

Q. Does that complete your education pretty well?—A. It does.

Q. Then, for your experience, what do you say?—A. I have been with the Food & Drug Administration since 1913. 230 I am a member of several technical societies, and I am a fellow of the American Association for the Advancement of Science, a member of the Botanical Society of Washington, and other organizations.

Q. And you for some 27 years, you have been engaged, I take it, in this field of examination exclusively or analysis under the microscope for the Food & Drug Administration?—A. I have, yes, sir.

Q. I suppose during that period you have examined a great many samples?—A. Oh, hundreds of miscellaneous samples.

Q. And did you make some microscopic examination of some of the sample in this case, Mr. Keenan?—A. I did.

Q. And did you use in the course of that examination, under a microscope, a portion of the tablets in Exhibit Number 3?—A. I did.

Q. And did you also use in that examination a portion of the tablets in Exhibit 15 in evidence?—A. I did.

Q. Now, what was the purpose of your examination under a microscope?—A. These samples were submitted to me for the purpose of determining whether they were identical or different.

Q. And you then proceeded, I take it, to make your microscopic examination?—A. I did.

Q. Tell us what you did.—A. I powdered the tablets from these specific samples, and by my usual technique made portions of each sample and—

The COURT. Are we going ahead on the analysis of the exhibit, Exhibit 15?

Mr. FLEISCHMAN. We are going ahead on—

Mr. DORAN. Well, we have this, Exhibit Number 15, your Honor, for the purpose of identification.

231 The COURT. I know what it is, the sample Slade took on the 28th of May 1940.

Mr. DORAN. Yes; which Mr. Dotterweich said comes from the same batch.

The COURT. Are we going ahead on the analysis for potency?

Mr. FLEISCHMAN. I assume there will be admission on that, that it was potent up to the requirement of the U.S. P.

Mr. DORAN. No.

Mr. FLEISCHMAN. If that is not so I will have to put Mr. Miller back on the stand.

The COURT. You are trying to prove now either it is the same or a different sample?

Mr. DORAN. I think they are identical.

The COURT. What difference does it make?

Mr. DORAN. My purpose is to show that.

The COURT. Then you will have an analysis for the potency?

Mr. DORAN. As far as I know there is no need, it was stated they are from the same batch, and there was only one batch there. That is the point and we want to show the difference in identity, that there were two different sets of tablets there. The claim was made there was one batch of tablets and an effort has been made to show by the defense that the sample here in question, that was shipped, that that came from that one, that it is also admitted and claimed that this other sample was the same. The fact is, and we intend to show that there wasn't an identity, that they were different.

The COURT. All right.

(Discussion off the record.)

232 Mr. FLEISCHMAN. Will the District Attorney concede that the digitalis content of Exhibit 15 was beyond the requirements of the Government insofar as the sufficiency is concerned?

The COURT. Do you mean the strength and potency of the digitalis content?

Mr. FLEISCHMAN. The strength and potency.

Mr. DORAN. Let us take one matter up at a time.

MR. FLEISCHMAN. Then I will have to reopen the case and put Mr. Miller on the stand.

MR. DORAN. You can put him on but let us take one matter at a time.

Q. What did you do?—A. I followed my usual technique, and examined these tablets from these specific samples, powdered them in a mortar, and got them to a fine degree of granulation and examined them microscopically, and I found in the sample number 3 that there was considerable more starch than in sample 15.

Q. What is your opinion, as an expert, as to whether or not the tablets from these two sets of samples were from the same batch?—A. It wouldn't be from the same batch.

Q. Is there any other sort of thing, anything else that you did in the course of your test, to come to your conclusion?—A. I also took advantage of the fact that the starch was stained to back up the aqueous iodine solution, and for that purpose I mounted other samples of the same product, both of these products in respective drops of iodine solution. Sample number 3 showed by this staining that it contained considerable more starch than sample 15.

Q. When you say sample 15, you refer to Exhibit 15, and Exhibit 3?—A. Yes.

233 Q. That is, there was considerable more starch in the tablets in the bottle; Exhibit 3?—A. That is it.

Q. And I take it from what you said, it is a different color?—A. It is a staining reaction which is significant for starch.

MR. DORAN. I would like to have that demonstrated, your Honor. There are things he has to bring in before long.

THE COURT. I would like to finish this evidence if I can this morning.

THE WITNESS. I will take half or three-quarters of an hour.

THE COURT. Do what we can now.

MR. DORAN. Go ahead and get it.

(Short recess.)

THE WITNESS. I want sample number 3.

(Witness producing apparatus for making demonstration or test before the jury.)

THE WITNESS. I am not powdering up Exhibit 15. The first I powdered was Exhibit 3. That is a bottle of distilled water [indicating], this is a bottle of iodine water [indicating]. I take one drop of distilled water. This is for the purpose of diluting the reagent. This is my iodine solution [indicating]. See the difference in the color of these?

MR. FLEISCHMAN. I suppose we are entitled to take a look.

THE WITNESS. Yes, sir. See the difference in color of these?

Mr. FLEISCHMAN. I don't see any difference. However—
 Mr. DORAN. I object to the comment of counsel. You are not on the stand.

234 The COURT. He can see the purpose of the experiment, and to show the difference in color and then he can show to the jury and let them make up their mind if there is a different color.

The WITNESS. My idea is, I may add the iodine solution to the tablet content, and you will get a deeper color than will with the tablet containing the smaller amount of starch.

Mr. DORAN. Tell us the difference in color with respect to the Exhibits 3 and 15.

The WITNESS. Exhibit 15 is different starch color than Exhibit 3.

Mr. FLEISCHMAN. May I give this to the jury?

The COURT. Yes.

The WITNESS. Of course, a demonstration like this is difficult to put over to a layman who is not an expert. Your Honor will appreciate that.

The COURT. I can appreciate that.

The WITNESS. And I don't know anything about their work either.

Mr. FLEISCHMAN. I agree with that.

Mr. DORAN. I object to that remark.

The COURT. No; he said he didn't know anything about my work.

Mr. FLEISCHMAN. May I cross-examine him?

Mr. DORAN. Are you finished with your demonstration?

The WITNESS. Yes; I am.

Cross-examination by Mr. FLEISCHMAN:

Q. Mr. Expert, let me say at the outset, that I know nothing about it, I wouldn't know what you put in, or anything else, that is your business.—A. Sure.

235 Q. But I take it if you put a drop of iodine more in one than in the other, you get a darker picture?—A.

Well—

Q. You know if you put in a single fraction of a drop more, or any such figure of speech, in the one than the other, you get that result?—A. Yes; and your starch in the sample would be the only ingredient to absorb the iodine.

Q. And do you hold with me on that, if you will add or do anything with any of the ingredients?—A. No, sir.

Q. You want this jury then to believe, if one is lighter in stain of the iodine than the other, to say there is a difference?—

A. To amplify the other test. I also made a microscopic demonstration.

Q. What you mean to say, to put it short and blunt, when these men testified that they came from the same sample in granulation, that they are not telling the truth, is that so, in substance?—A. I didn't say that.

Q. What else are you saying then?—A. These samples were submitted to me for the purpose of determining if one lot or different lots. That is all I had to know.

Q. We have had two men here who have testified, or one man, anyway, that he made up the batch of this stuff, and sold to another, and then samples taken from both—

The COURT. That is not the testimony at all. This man from the Arner Company testified to Exhibit Number 15, that is the exhibit that they took, and he testified that they made up one batch, and the Buffalo Pharmacal got it all. Mr. Meier didn't testify where Exhibit 15 came from. You have intimated he did.

Mr. FLEISCHMAN. What is Exhibit 15?

236 The COURT. That represents what Slade took from the Buffalo Pharmacal Company in May.

Mr. FLEISCHMAN. Very true. Slade pounced down on the Buffalo Pharmacal Company and took it from the same batch. He had given from the same batch, so you have the same thing.

The COURT. He didn't testify to that. He testified that the sample he gave, that come from another batch.

Mr. FLEISCHMAN. No.

The COURT. Exhibit 15 came from another batch.

Mr. FLEISCHMAN. Excuse me. You are through.

The WITNESS. Thank you.

ARTHUR J. MEIER, recalled, testified further as follows:

Redirect examination by Mr. FLEISCHMAN:

Q. Perhaps I overlooked something and for the purpose of clearing it up: The control sample came from what batch? —A. Batch number 1.

The COURT. I understand that.

Q. That is the batch we are talking about, the first batch that you sold to the Buffalo Pharmacal Company?—A. Yes, sir.

The COURT. That is perfectly clear and simple, a sample from that went to Penick & Company.

Mr. FLEISCHMAN. That is what I mean.

The COURT. I am talking about Exhibit 15.

Mr. FLEISCHMAN. Exhibit 15 is his control sample.

Mr. DORAN. No; it is not.

237 Mr. FLEISCHMAN. Then he had no reason to bring it in. Is that something that he substituted; is that it?

Mr. DORAN. I don't claim that. Don't make any horseplay. Your client said it was from the same batch.

Mr. FLEISCHMAN. If not, what has Exhibit 15 got to do with this case? I don't know anything about it, if not substituted.

Mr. DORAN. That is the most unfair charge I ever heard made. When his own client took the stand, he identified it. I wish you would retract that statement before you make charges of that kind.

Mr. FLEISCHMAN. What has the second batch got to do with this case?

The COURT. Nothing.

Mr. FLEISCHMAN. If it came into evidence, how did it?

Mr. DORAN. It isn't; it is all play. His own counsel stood here and told him that. If you are trying to confuse, do it, but don't misrepresent.

Mr. FLEISCHMAN. I think I have tried cases with this office twenty years, and I don't think I have ever been accused of doing anything not entirely fair, and if I am, let him rise and say so.

Mr. DORAN. You have; you have tried to infer to the Court, to show time and time again that Exhibit Number 15 is something else than your own client said.

Mr. FLEISCHMAN. May I move to strike out all reference to Exhibit 15 on the ground that it doesn't concern the first batch; that it isn't the first batch and nothing to do with this case.

238 The COURT. No; it is in evidence.

Mr. FLEISCHMAN. What is its relevancy; what possible connection has it?

The COURT. As I understand your contention, you contend with reference to Exhibit 15 that the Buffalo Pharmacal Company only had one kind of digitalis and the State got it and gave their blessing and all right. They are trying to prove now you had two batches.

Mr. FLEISCHMAN. What the State took was batch number 1.

The COURT. Well, if it is, you can from batch number 1, then it should probably stay in evidence. That is Exhibit 15.

Mr. FLEISCHMAN. No; it is not.

The COURT. You just said it was.

Mr. FLEISCHMAN. Mr. Whissel, would you straighten me out—

The COURT. No, no. I know what the testimony was. This sample, Exhibit 15, was taken by Slade, from the Buffalo Pharmacal Company on May 28, 1940.

Mr. FLEISCHMAN. That is batch number one.

The COURT. I don't know.

Mr. DORAN. Your client testified it was batch number one.

Mr. FLEISCHMAN. Then we are only in agreement if you were talking about that batch number 1.

The COURT. Your client said batch number 1. They are trying to say it isn't batch number 1.

239. Mr. FLEISCHMAN. Perhaps I am all wrong, and I want to apologize if I am. If this thing, as argued, if it is batch number 2, it doesn't belong here, but the mistake or error was, I supposed it was batch number 2, which, of necessity, would be different from batch number 1. This is batch number 1 and therefore does belong in this case. Am I correct now?

The WITNESS. I don't know anything about that.

Mr. FLEISCHMAN. But the sample you gave them was batch number 1!

The WITNESS. From my control file.

Mr. FLEISCHMAN. There is always a difference between batches. Are they alike absolutely? Is that possible?

The WITNESS. Not absolutely.

Mr. FLEISCHMAN. But each batch that was taken from batch number 1, is alike?

The WITNESS. Yes.

Mr. FLEISCHMAN. That is clear.

The WITNESS. As far as our production is concerned, of course.

LLOYD C. MILLER, recalled, testified further as follows:

Direct examination by Mr. FLEISCHMAN (continued):

Q. Mr. Miller, you got from the State of New York, did you not, a sample of digitalis that had been seized by the State of New York from the Buffalo Pharmacal Company for analysis?—A. No; I don't believe so. To the best of my knowledge, I received this bottle, and which says on it—

240. The COURT. If that has not been identified, let us not talk about it.

Q. This marking is Exhibit 15. Are these your markings on here?—A. None of my markings on here. The first time I saw it was the day before yesterday.

Q. But when you saw it, it was from the files of the District Attorney's office, in their possession and custody?—A. Yes.

Q. Not from me?—A. No.

Q. Did you examine that?—A. I made no examination of this whatsoever.

Q. Whatever examination you made of the seizure, that was made by the State of New York on the premises of the Buffalo

Pharmaceutical Company. Did you make a report on it?—A. No; I have been trying to say that the only examination that I made—

Q. I don't care where examined, but whatever examination you made for them, did you notify the Buffalo Pharmaceutical Company about its product in so far as the digital content is concerned?—

A. No.

Q. You mean that, although you didn't approve of it, that the State of New York said, "Go ahead, it is all right," if they did so state—

Mr. DORAN. I object to the form of the question. You are trying to assume something that is not the fact. If you are confused, you had better straighten yourself out. Don't assume of this witness, that he made an examination of the sample from the Buffalo Pharmaceutical Company and try to get him to say he did.

Q. If you are not the man who made the examination, who did in your department?—A. I made the only examination that was made—I made an examination of materials submitted to me from the Buffalo Pharmaceutical Company, in the regular course of our inspection routine, and it was half strength.

Q. Do you want to tell this jury that whatever examination you made, and which I am told you made from the State of New York Board of Pharmacy, and which was half strength, and that the State of New York, despite your report, that they said to go ahead?—A. I have not said that the material from the State of New York was half strength; it was not.

Q. What strength was it?

Mr. DORAN. Don't infer it was something from the Buffalo Pharmaceutical Company; don't be afraid to ask him.

The COURT. Ask him if he examined the sample submitted by the State of New York, and then ask if he knows where it came from.

Q. All right. Do you answer that you know it?—A. I received this sample, purporting to come from the State of New York, yes; and I analyzed it.

Q. Where did the State of New York, if you know, take the sample from?—A. I think I can only guess from the label, and things like that, and to the best of my knowledge, it came from Arner & Company.

Q. Did you examine it?—A. Yes.

Q. Did you find its strength?—A. Yes.

Q. What was its potency?—A. Approximately 80 percent.

Q. And that is within the limit of the U. S. Code?—A. The lower limit.

Q. And if you reported that to Slade, he would have
242 to report O. K., and lift the quarantine?—A. That is all
I said.

Mr. FLEISCHMAN. That is all.

The COURT. This confuses me. Just a moment. This is im-
portant. Here is testimony on the analysis that came from Arner
& Company, that has nothing to do with this case, unless it is
from batch number one. How is it material?

Mr. FLEISCHMAN. That is very true. I have proved here that
the only thing that was taken by New York State was from batch
number one, the only thing we had at the time and examined by
them and told to go ahead, that the quarantine was lifted.

The COURT. How do I know or the jury, what he examined and
said was 80 percent, came from you?

Mr. FLEISCHMAN. He said it was the only one.

The COURT. He said it came from Arner and Company and we
don't know what batch it was.

By Mr. FLEISCHMAN:

Q. Tell me this, please, Doctor, who can I get the information
from? If you will tell me, I will be glad to get it, as to
where this sample submitted to you came from.—A. I expect you
might get the man that collected it.

Q. Slade?—A. I suppose.

Q. Do you know him?—A. No.

Q. Will you at my expense ring Mr. Slade and ask him if he
would be able to tell us where he got the sample from?

Mr. DORAN. I object to that.

Mr. FLEISCHMAN. Well, it would save me bringing him down.
I was trying to be saved that trouble.

Q. Can you tell from the handwriting on there, or anything
about it that you identify on this bottle?—A. Well, I have seen
this bottle in Mr. Doran's office.

243 Q. And outside of that?—A. Before, I hadn't seen it
all.

Q. You don't know that the bottle you now hold in your hand
was taken from Arner and the other from the Buffalo Pharmacal
Company, you don't know that?—A. No.

Q. Is there anyway you have of checking up on that to be able
to give us a report within a reasonable time?—A. The numbers
don't seem to agree on the two bottles I have.

Q. They are, of course, each number by every concern dif-
ferent?—A. I will be glad to read on this one which reads:
"Digitalis tablets, 1½ grains, 1 U. S. P. unit, the Arner Com-
pany, from New York State Board of Pharmacy. Sample
85,151." And there are initials on there "H. F., 6-12-40."

Q. I want to get from you, can you find out if they put "Arner & Company" on there, they did put on the manufacturer, why didn't they put the other name on there?—A. No.

Q. Can you, at my expense, find out?—A. I don't know where Mr. Slade lives.

Q. Will you try to do it?

The COURT. Wait a minute. You are asking him to make your case for you. If you want him to give an analysis of some sample that you identify, that is simple for him. I don't want you to put this witness in that light. He is under no obligation.

Mr. FLEISCHMAN. No; except in the interest of justice.

The COURT. That is all right.

244 **ARTHUR J. MEIER**, recalled, testified further as follows:

Redirect examination by Mr. FLEISCHMAN:

Q. I show you a bottle marked Exhibit 16 for identification and I ask you whether this bottle was taken from your place, and if so, by whom?

The COURT. I will not have that all over. That was from batch number two. Why have it again?

Mr. FLEISCHMAN. I wish to prove that the other one was not taken from his place.

The COURT. All right, then, leave Exhibit 16 alone. I want the proof on that.

Q. Mr. Meier, I will show you a bottle purporting to have come from your place and ask you whether this ever came from your place, this bottle?—A. That bottle did not come from our place. The sample, I testified previously.

Q. Wait a minute. This bottle I am talking about did not come from your place?—A. No.

Mr. FLEISCHMAN. Mark it for identification.

(Bottle marked "Defendant's Exhibit H" for identification.)

JOSEPH H. DOTTERWEICH, recalled, testified further as follows:

Redirect examination by Mr. FLEISCHMAN:

Q. I show you Exhibit H for identification and ask you whether or not you know anything about this bottle?—A. I don't remember seeing this.

245 Q. Did you turn over to the State of New York, or how did the State of New York take the sample of your product?—A. They took care of the whole thing themselves. Mr. Slade takes his own program of quarantining and seizing the thing; he does it all himself.

Q. Did you see whether he took a sample of any kind, a bottle at all?—A. Yes; he took a sample along.

Q. Do you know the kind of a bottle it was?—A. I don't remember.

Q. And whatever he took from you as a sample was from what batch?—A. Batch number one.

Mr. FLEISCHMAN. That is all.

The COURT. How many samples did he take?

The WITNESS. Just one that I remember.

The COURT. Now, we have Exhibit 15.

Mr. DORAN. That is right.

The COURT. Which is the sample that Slade took on the 28th of March 1940?

The WITNESS. That is the one.

Mr. DORAN. He identified that on May 28, 1940.

The WITNESS. I am sorry, but I do recall he purchased one bottle from us, it just comes to me now. He came in and he said he had to buy a bottle and laid down the money, thirty or forty cents, and he purchased the bottle.

By the COURT:

Q. That was May 1940?—A. On the same day that he seized the lot, they quarantined and seized the lot. I asked him, I said, "Well, why do you want to buy a bottle of this?" and eventually, after a little while he said, "I have to seize the lot and in order to do that I must make the purchase." And that just comes to my mind now.

246 Q. Now, you say that all of the digitalis that you had that day in your plant was from batch number one?—A. That I don't recall.

Q. Well, how do you recall he took the sample from batch number one or number two?—A. Because it was on our shelves.

Q. What is the other then?—A. I don't remember any other.

Q. How do you know that was not on your shelf?—A. I don't quite understand.

The COURT. And I don't either.

Mr. FLEISCHMAN. When Slade came into your place and quarantined it, did you have in stock batch number one or batch number two, do you know?

The WITNESS. We had batch number one, of that I am sure, but I don't know if batch number two. I don't know. If you ask me to look at the record—

Mr. FLEISCHMAN. I wish you would. You can telephone and find out from your records.

The WITNESS. I wrote it down without looking it up.

Mr. FLEISCHMAN. Does it answer the question?

The COURT. As far as it goes, but it doesn't go far. I still say, if he doesn't know, how will he identify the batch that Slade took? Can you tell us that?

The WITNESS. I think I told you that Mr. Slade took a sample out of the lot that I closed up and sold, and quarantined—

Mr. FLEISCHMAN. The stuff he sold and quarantined is what stuff?

The WITNESS. One; no question about that.

247 By the COURT:

Q: How do you know that; it wasn't marked batch number one?—A. They were all booked up and down, up on our shelves; all booked and sealed up, standing there.

Q. What about batch number two?—A. That I don't know, that is, I don't know if we had any on hand.

Q. If you had batch number two it would be on your shelves?—A. No; you are wrong.

Q. I may be.—A. That is very easy. Now, I don't know if we had batch number two on hand or not. If we did, it would not be on the stock shelves, because we have a policy that the things on the shelf must be used first, before anything else is touched. There is an object behind that, so that our employees do not start using new material and let the old remain on the shelves, when it might get older and older. Our shelves must be cleaned up of the old things before we touch the new.

Mr. FLEISCHMAN. That is all.

Re-cross-examination by Mr. DORAN:

Q. You were very definite to my recollection in your statement to me what Mr. Slade picked up was batch number one, you were definite on that?—A. Well, he took it off the shelf.

Q. You mean to say you didn't testify that what Mr. Slade picked up was from batch number one?—A. Yes, sir.

Q. You didn't?—A. I said he took it off the shelf and that is batch number one.

Q. Do you want the jury to understand that I didn't ask you?

The COURT. He said it was from batch number one.

248 The WITNESS. I said it three or four times.

Mr. DORAN. If Mr. Slade took it—

The WITNESS. Yes; and I still say so.

Mr. DORAN. All right.

Mr. FLEISCHMAN. The defendant rests.

The COURT. Is the evidence closed?

Mr. DORAN. Yes.

The COURT. We will recess until 2:15 P. M.

(Recess until 2:15 P. M.)

After recess, 2:15 P. M.

Mr. DORAN. I wish to recall the defendant for a few questions.

JOSEPH H. DOTTERWEICH, recalled, testified further as follows:

Re-cross-examination by Mr. DORAN:

Q. I believe you testified this morning that you knew nothing about this shipment of the bottle of digitalis, I take it.—A. Until I got the citation.

Q. So that you personally, you mean that you personally had nothing to do with the shipment of that bottle?—A. No.

Q. I think you further testified that bottle came out of what you call batch one tablets, the first batch of tablets that you had shipped to you from Arner & Company?—A. Yes.

Q. Now, having nothing to do with that personally, I take it you knew nothing about it except what possibly someone in your organization has told you?—A. In what way do you mean?

249 Q. I mean by that, it is not personal knowledge on your part about this bottle that was shipped to Dr. Tagett coming out of that batch?—A. The chances are that I never saw the bottle.

Q. So that in stating that it came out of the first lot, you don't know that of your own knowledge, do you? That is, you don't do that work.—A. No; of course not.

Q. So your former statement that it came out of a batch you had, but shipped to you from Arner & Company, that is something you checked up with your employees and not your own knowledge?—A. Checked up from the employees and records when it came into the place, broken up, and put on the shelves.

Q. So it was not your own knowledge excepting as you got it from other people?—A. Yes.

Mr. DORAN. That is all.

Mr. FLEISCHMAN. That is all, Mr. Dotterweich.

Mr. DORAN. Well now, your Honor, I move, in view of the testimony of this witness, to strike out the testimony of Dr. Chapman with respect to his analysis, on the ground it hasn't been connected up properly. That was the understanding of the concession made yesterday.

The COURT. I think I will let it stand.

Mr. DORAN. I make my motion.

The COURT. I deny the motion. Exception please.

Renewal of motions

Mr. FLEISCHMAN. We respectfully renew all motions that have previously been made and with the same force and effect as if

they were made now, and the motions for a directed verdict just as they were made before a motion was denied.

Will your Honor be kind enough to instruct the jury as to the law?

250 The Court. The same admonition, that it is a question of law on these denials.

(Mr. Fleischman sums defendants' case to the jury.)

(Mr. Doran sums the Government's case to the jury.)

Charge of the Court

Members of the Jury, in this case, there are two defendants, the corporation, the Buffalo Pharmacal Company, and Joseph H. Dotterweich. Both defendants are charged in the information laid against them with violation of the Federal Food, Drug & Cosmetic Act, as the law is officially known. It was formerly known as the Food & Drug Act, and for the purpose of brevity, will be so referred to in this case.

The violations relate to two separate shipments in interstate commerce. The first was a shipment of cascara compound on October 2, 1939, shipment having been made from the defendant's Buffalo plant to the office of Dr. Palmer, in Homer City, Pennsylvania. The second shipment was made on January 9, 1940, and consisted of digitalis tablets which were shipped from the defendant's Buffalo plant to Dr. Tagett in Ohio. What I will call for the purpose of this trial the first count of the information, it charges both defendants with misbranding the cascara compound which was shipped to Dr. Palmer. The information charges that the statement on the label "Tablets, cascara compound (Hinkel)" is false and misleading in that the statement on the label purports to represent that the article consisted 251 of tablets of compound cascara (Hinkel), a drug recognized in the National Formulary under the name of "Compound pills of cascara," and "Hinkel's pills," whereas said article did not consist of tablets of cascara compound (Hinkel) because the article shipped contained strychnine sulphate, an ingredient not included in the formula set forth as standard in the National Formulary. The statute prohibits the shipment in interstate commerce of any drug that is misbranded. The term "drug" includes any article recognized in the official United States Pharmacopeia or the official National Formulary, or any supplement of either of them. The statute further provides that the drug shall be deemed to be misbranded if this label is false or misleading in any particular.

The charge therefore is in short that the statement on the label attached to the cascara compound tablet was false or misleading.

There is no question about the shipment having been made. The question for your determination is "Was the drug misbranded," or to state it another way, "Was the label false or misleading in any particular?"

The statement on the label of the article shipped to Dr. Palmer was as follows: "Tablets cascara compound (Hinkel)." In addition to that designation on the label there was set forth the material ingredients of the tablets in the bottle. That statement included the ingredient of strychnin sulphate. The analysis established that the tablet contained the ingredients particularly set forth on the label, including strychnin sulphate. The gist of the charge is that the legend of the particular ingredients set forth on the label, that the designation "Tablets, cascara compound (Hinkel)" was false and misleading, because at the 252 time of the shipment, the National Formulary recommended a drug known as "Compound pills of cascara" or "Hinkel's pills." The formula contained in the National Formulary in effect at the time of the shipment did not contain strychnin sulphate for the drug known as "Compound pills of cascara," or "Hinkel's pills."

The evidence shows that prior to January 1, 1939, the formula for that drug in the National Formulary had contained strychnin sulphate, but that in January 1939, it had been deleted, or taken out of the formula. The defendants assert in defense of the charge of misbranding that the drug that they shipped to Dr. Palmer in Homer City, Pennsylvania, was not "Compound pills of cascara" or "Hinkel's pills," the drug recognized in the National Formulary in effect at the time of the shipment, but that they were something else, to wit: They designated the drug on the label of the bottle "Tablets Cascara Compound (Hinkel)," and that designation on the label, together with the listed ingredients, was not false or misleading, and did not constitute misbranding.

If you conclude from all the evidence that there is a real distinction between the drug recognized in the National Formulary as "Compound pills of cascara" or "Hinkel's pills," and the drug labeled as "Tablets cascara compound (Hinkel)," and that the manner of labeling used by the defendant corporation was not false and misleading, and would not lead a purchaser into believing he was purchasing the official article, then it is manifest that no violation of misbranding has been proved within the contemplation of the first count of the information. If, on the other hand, you conclude that the manner of labeling 253 used on the bottle, that is, the designation "Tablets cascara compound (Hinkel)," together with the list of ingredients including strychnin sulphate, was false and misleading in

that it would lead the purchaser or the general public to believe that the drug contained only the ingredients as designated in the formula for "Compound pills of cascara," or "Hinkel's pills," as contained in the National Formulary, then, of course, your conclusion would have to be that the labeling was false and misleading and constituted misbranding.

What I will call the second and third counts of the information, relate to a shipment of digitalis to Dr. Tagett in Ohio. The second count charges that the drug when shipped was adulterated in that its strength differed from, and its purity or quality fell below that which it purported or was labeled to possess in that tablet of digitalis as it was represented to possess, a potency of one United States Pharmacopeia unit, whereas each tablet possessed a potency of less than one-half of that.

The third count charges that the digitalis when shipped in interstate commerce was misbranded, in that the statement on the label incorrectly labeled the potency of the digitalis contained in the bottle. As I said in relation to the first count, the statute prohibits the shipment in interstate commerce of any drug that is adulterated or misbranded. The term "drug" means an article recognized in the National or the United States Pharmacopeia or the National Formulary, or any supplement of them. The statute provides the drug should be deemed to be adulterated if its strength differs or its potency falls below that which it purports or its represented to possess. There is no question regarding the shipment of digitalis. It was shipped in interstate commerce to Dr. Tagett in Ohio.

Regarding the charge contained in count two of the information, the question for your determination is "Was the digitalis adulterated," or to state it in another way, "Was it of less strength than the standard"? The evidence upon the part of the Government establishes that upon analyses made on March 4, 1940, the digitalis tablets contained in the shipment, were of a potency of less than one-half of that prescribed by the official United States Pharmacopeia. Mr. Meier said that he sent the control sample of batch number one of digitalis to Penick & Company in May 1940. Dr. Chapman said that he analyzed a sample from Penick & Company in June 1940, and that its strength was 80 percent of one unit. His report says "The potency is at the lower limit permitted by the U. S. P." Mr. Dotterweich says that the digitalis in question came from the number one batch. If you are satisfied that the digitalis in question came from the number one batch, and if you are satisfied that Dr. Chapman analyzed the sample from the same batch, then you have a right to consider his analysis in determining whether the digitalis in question was below standard.

There was another sample analyzed by Dr. Miller, which contained 80 percent strength. The source of that sample you must determine from the evidence of Dotterweich who said it was from batch number one. He had no knowledge of when the first shipment of batch number two had been received by his company, or at least, he had no present information about it. Of course, the analysis of either Dr. Chapman, or the analysis of Dr. 255 Miller, as to this second sample received from the State

Bureau of Pharmacy is of no value at all unless you are satisfied from the proof that the source was identical to that from which the questioned sample came. When I say "Source," I don't mean the company or supplier, but the identity of the particular batch. Unless all the samples came from the same batch, we should have no concern about what the analysis of any one was, no matter who made it. The identity of and source of the questioned digitalis, and that found by the State authorities is brought to question by the testimony of the chemist or analyst, who performed the experiment here. He gave as his opinion that the two samples, the one, the questioned digitalis, the other that taken by the State authorities, did not come from the same source. If you believe that, and if you believe that the second sample that Dr. Miller tested and found 80 percent strength, came from that which the State took, then the analysis is of no value in determining the issue here.

In regard to this shipment of digitalis and constituting the third count of the information, which is the charge that the digitalis was misbranded. The label on the product was "Tablets digitalis, 1½ grains, one U. S. P. unit." If you are satisfied from all the evidence that the strength of the digitalis tablets or their potency fell below 80 percent of one U. S. P. unit per tablet, then you are warranted in finding that the digitalis tablets were adulterated and were misbranded; because the label represented them, that the tablets contained one U. S. P. unit. Of course, you will recall that the margin of error or liability in the test was 20 percent, so 80 percent was admissible.

256 We have heard a lot of testimony about the frog test in ascertaining the strength or potency of digitalis. That method is prescribed by the official compendium known as the United States Pharmacopeia. Unless you are satisfied from the evidence that, in spite of the fact that the frog test has been adopted by Congress as the official method of testing the potency of digitalis, that the test is inaccurate and is of no value to that end, then you must accept the tests by the experts who made them, unless you have good reason to question the credibility of those experts who made the test. You may not arbitrarily and without reason reject the evidence of the tests.

The question of credibility of all witnesses is up to you as jurors and that applies to expert witnesses as well as the lay witnesses. You will consider their qualifications, their educational background, and their ability to give opinions as to matters regarding which they testified and make up your mind whether the testimony which they gave should be accepted. It is not for you as jurors, any more than it is within my province as the trial judge to question the wisdom of the provisions of the Food & Drug Act. It is sufficient to say that Congress in enacting the Food & Drug Act, was acting wholly within its power in prescribing regulations for interstate commerce in the interest and general welfare of the nation, and it is incumbent upon the Court and the jury to give full force and effect to the Food & Drug Act, and all of its provisions, regardless of whether some individual or individuals might have a different view whether the provisions were beneficial or not. There is no question in this case but that the shipments were made in interstate commerce. The contested question

257 relates solely whether the product in the case of the cascara compound was misbranded and in the case of the digitalis whether it was both adulterated and misbranded within the definitions as I have given them to you. Admittedly the shipments were made by someone connected with the Buffalo Pharmaceutical Company, the corporation. We also have as a defendant here, Joseph Dotterweich. As far as the question of his guilt regarding the charges in the information is concerned, the question is, if you find the product to be misbranded and adulterated, "Was he responsible for the shipment of them in interstate commerce?" In other words, are you satisfied from the evidence that the shipment of the cascara compound and the shipment of the digitalis were made under his supervision by him as "General Manager." It is not necessary for the Government to prove that he personally and physically made the shipment himself. It is sufficient if the evidence establishes to your satisfaction that it was made under authority conferred by him as general manager upon his subordinates, including the receiving and shipping clerk.

The charge in this case is a misdemeanor as distinguished from a felony. It is what might be called a police regulation enacted by Congress in the interest of public welfare. Different from most of the crimes with which the most of you are perhaps familiar, the element of intent to commit the offense is not a requirement under the statute. In other words, Congress has made it an offense to ship drugs in interstate commerce which are either misbranded or adulterated, regardless of the fact whether the shipper actually knew that the drug was misbranded or adulterated. It is the offense of shipping itself of such an article

258 and not the knowledge of the shipper that is made an offense by the statute. Now, that may not square with what some individual might believe the law ought to be but that is the law and we are bound by the law as we find it. So I say to you the question of good faith of the defendants, or the question of intent to violate the statute is not a question for your consideration at all in this case. At first blush, that might seem harsh or unreasonable that the statute should make it an offense regardless of intent, but Congress saw fit to place it within the law that the shipper might acquire a guarantee for the purchase of the drug from a supplier; so that was a provision included by Congress, this provision on lack of intent.

The burden is upon the Government to establish misbranding in connection with the cascara compound and adulteration and misbranding in regard to the digitalis and to establish the guilt of either of the defendants or both of them with respect to said charges beyond a reasonable doubt. A reasonable doubt is such a doubt that arises from something in the evidence or from some lack of evidence and which creates in your minds as jurors a question as to the guilt of the defendants or either of them. It is a doubt that has a foundation. If you have such a doubt in regard to either of the defendants upon any of the charges, that doubt would require you to acquit in regard to the particular defendant and in regard to the particular charge as to which you have such a reasonable doubt. If, on the other hand, you are convinced that the Government has sustained the burden of the proof upon it, and has demonstrated the guilt of the defendants, or either of them, beyond a reasonable doubt, it is your duty to convict.

There are three separate counts. Each is a particular and separate offense. Each defendant is entitled to a 259 separate consideration of the case. In other words, the corporation is entitled to a separate consideration of each particular charge against it, and the individual Joseph Dotterweich is entitled to a separate consideration on each particular charge against him, and any verdict which you return should show that you have considered the guilt of each defendant upon each particular charge. You may find one or both guilty or not guilty upon any or all of the three separate charges.

Now, I have referred to some testimony here in my charge and that testimony only comes from myself, and from my recollection. You are not bound by it. If your recollection of the testimony is different than mine, you will follow your own, as you are in just as good a position to know what the evidence is as I am. You, in other words, are the sole judges of the facts.

in this case. It makes no difference to you what I may think about the case. I tried not to indicate what I think about it, but whether I did or not, you are not bound by what I think about it, you are to follow your own conclusions and then to follow the law as I gave it, and the facts as you have found them. The responsibility of that duty is yours. You are the sole judges of the weight of any of the testimony that has been given here. That includes the expert as well as the lay witnesses, and if you believe that any of the witnesses who have testified here has an interest in the outcome of this case, you have a right to consider that person's interest and evaluate that testimony and give it such weight as you want to give it.

Anything else that you would request?

Mr. DORAN. No requests for the Government.

Mr. FLEISCHMAN. Your Honor, I think you have given a very fair charge, but I ask you to say to the Jury that unless they find beyond a reasonable doubt that the goods—
260 and I am talking now about the digitalis that left the defendant's place of business—insufficient under the law, unless they so find beyond a reasonable doubt that they cannot convict.

The Court. Well, I think that would only confuse them. I have tried to outline all of the elements that are necessary to constitute this claim. Now, the burden is upon the Government to establish each and every one of those elements beyond a reasonable doubt. I think I will only confuse them if I—

Mr. FLEISCHMAN. Then I will withdraw that request, your Honor. I ask your Honor to say then, in view of the District Attorney's summation that the jurors need not assume that any witness because of inability of the other side to prove—let me state it specifically with regard to Dr. Tagett, that the fact that we are unable to show that his jar fell over or some other things, or heat, or something else that we are not able to prove, that they are not to assume that it didn't happen.

The Court. That is merely another way of really determining the weight to put on any testimony. If you believe it, all right, and if you don't believe it, then throw it out.

All of the exhibits may be taken to the jury room now.

Mr. DORAN. There was a letter, that letter of January 9, 1940, I only offered part of it. The body of the letter contained something that had nothing to do with the case.

The Court. That is of no significance, leave that out.

The two alternate jurors are excused.

(The Jury retired for deliberation at 4 P. M.).

Oct. 17, 1941

George L. Grobe, United States Attorney, Attorney for the United States of America (Joseph J. Doran, Assistant United States Attorney, of Counsel).

Robert J. Whissel and Samuel M. Fleischman, Attorneys for the defendant Joseph H. Dotterweich.

The defendant, Joseph H. Dotterweich, moves to set aside the verdict of the jury upon the ground that it was against the law and against the weight of the evidence, that the verdict as to the defendant Dotterweich was inconsistent with the disagreement of the jury in regard to the corporate defendant and, therefore, an illegal verdict, and that the failure of the Government to prove notice to the defendant Dotterweich of an intended prosecution under the Food, Drug, and Cosmetic Act, June 25, 1938, c. 675, 52 Stat. 1040 was a condition precedent to the commencement of a proceeding against him, without which there could be no valid proceeding.

There was sufficient evidence upon which the jury could base a verdict of guilty. The verdict was not inconsistent with the jury's treatment of the corporate defendant as to which it reached no verdict. Notice pursuant to Section 335, Title 21, U. S. C. A. of a contemplated criminal proceeding was given to the corporate defendant. Dotterweich was the General Manager and had actual notice of the contemplated proceeding against the corporation. There is nothing in the statute limiting prosecutions to those cases that have been reported by the Secretary to the United States Attorney. Prosecution for violation of the statute arising independently of any report by the Secretary would

require no preliminary notice. The absence of such a 262 limitation indicates that the requirement for notice under

Section 335 should be construed as an administrative provision imposing a duty upon the Secretary. The reasoning adopted by the Supreme Court in United States vs. Morgan, 222 U. S. 274, in construing a provision for preliminary notice under the former statute, Section 4, Pure Food and Drug Act of June 30, 1906, 34 Stat. L. 768 C. 3915, applies with equal force to the notice required under the present statute. It was there held that the requirement for notice was not jurisdictional. I think the same reasoning impels a like conclusion here.

Motion denied.

Dated Oct. 17, 1941.

HAROLD P. BURKE,
United States District Judge.

In United States District Court

Notice of Appeal

Oct. 30, 1941

Name and address of appellant: Joseph H. Dotterweich, 36 Brunswick Boulevard, Buffalo, N. Y.

Names and address of appellant's attorneys: Robert J. Whisell and Samuel M. Fleischman, Buffalo, N. Y.

Offenses: Violation of the Federal Food, Drug & Cosmetic Act, misbranding and adulteration of drugs in violation of 21 U. S. C. 331A, 351C, 352A, 351B.

Date of judgment: October 27th, 1941.

263 Brief description of judgments and sentences: The defendant-appellant, Joseph H. Dotterweich, was sentenced to pay a fine of five hundred dollars on one count and five hundred dollars on each of the other two counts, which latter was suspended. He paid the fine of five hundred dollars.

The above-named appellant, Joseph H. Dotterweich, hereby appeals to the United States Circuit Court of Appeals for the Second Circuit from the judgments above-mentioned on the grounds hereafter set forth and also appeals from the order denying the motion for a new trial, and from the order denying the motion to set aside the verdict upon the grounds that it was against the weight of the evidence and against the law and that the said judgment was inconsistent, and on all the other grounds mentioned in the order denying motion made at the conclusion of the case, which order is hereto annexed and made a part hereof, and from each and every part of said order.

Dated Buffalo, N. Y., October 30th, 1941:

JOSEPH H. DOTTERWEICH, *Appellant*.

Grounds of Appeal: A motion was made at the close of the government's case for a dismissal of the indictment and for the discharge of the defendants and for a directed verdict of acquittal of both defendants, upon the ground that the evidence did not justify a conviction, and upon the further ground that there was a reasonable doubt as a matter of law. The motions were denied and an exception reserved.

264 A motion was made at the conclusion of the whole case upon the same grounds as was made at the conclusion of the government's case, which motions were denied and an exception reserved.

A motion was made in due time that the notice required by Section 335 should have been given by the department to the

defendant individual before prosecution and that the proof showed that no such notice was given and that there should be a dismissal as to the defendant individual because of the failure of the government to give such notice. This motion was denied and an exception reserved.

A motion was made for the dismissal of the defendant individual, the appellant here, Joseph H. Dotterweich, upon the ground that he was merely the general manager of the corporation and even if the corporation did commit any offense, the offense was such as to constitute an offense mala prohibitum and did not require any intent on the part of the corporation, and that, therefore, the employee of the corporation could certainly not be held liable for the commission of an offense committed by the corporation without intent where he had no intent to commit any crime; and further, that if a guarantee in writing to the corporation defendant could have absolved the corporation from criminal responsibility, that the defendant individual, the appellant here, could not have demanded any guarantee in writing from the seller of this merchandise and, therefore, could not be prosecuted under this Act. That motion was denied and an exception reserved.

A motion was made to dismiss the indictment as against the appellant that in order to sustain a conviction of misbranding under Section 352 there must be a fraudulent intent proved. That motion was denied and an exception reserved.

265 A motion was made to set aside the verdict of the jury upon the ground that the verdict was against the law and against the evidence. That motion was denied and an exception reserved.

A motion was made to set aside the verdict of the jury upon the ground that the verdict was inconsistent in that the defendant corporation could not be absolved; or not found guilty, of a crime whereupon the same facts an employee of that corporation could be found guilty, and that, therefore, that verdict was inconsistent. That motion was denied and an exception reserved.

A motion was made to set aside the verdict of the jury upon the ground that the evidence clearly indicated and showed that there was no misbranding by any false and misleading statements as charged in the informations insofar as they related to "Tablets of Cascara Compound Hinkle," first, because they were not "Pills of Cascara Compound Hinkle" as indexed and as set forth in the National Formulary, the official compendium, but that they were tablets and that between "Pills" and "Tablets" there is a distinctly recognized difference in the medical and

pharmaceutical world, and which is clearly set forth in indexes of the National Formulary itself in designating pills and tablets of various kinds, and, second, that if there was any misbranding it was not done by the defendants but by the government, in following the National Formulary referring to pills of cascara compound Hinkle, in that Hinkle's pills for a century was a formula of one Dr. Hinkle, which required strychnine sulphate as one of the important ingredients, and which was in the defendant's product, and that the government directed that strychnine sulphate shall be removed, but still retaining the name "Hinkle Pills" which in fact is not Hinkle's at all, and, therefore, is false and misleading to doctors and pharmacists, and, third, that it is not unlawful to sell cascara compound pills or tablets with strychnine sulphate in them if clearly stated on the label, and that on the label of the defendant's product there was set forth precisely what the tablets of Cascara Compound Hinkle contained, and which is not prohibited by any regulation of the government, and, fourth, that no evidence was produced to show that any doctor or that any person was misled. That motion was denied and an exception reserved.

266 Dated Buffalo, N. Y., October 30th, 1941.

ROBERT J. WHISSEL and

SAMUEL M. FLEISCHMAN,

Attorneys for Appellant,

Buffalo, N. Y.

To:

Hon. GEORGE L. GROBE,

U. S. Attorney, Western District of New York.

Hon. MAY C. SICKMON,

Clerk, U. S. District Court,

Western District of New York.

In United States District Court

Assignment of Errors.

A motion was made at the close of the government's case for a dismissal of the indictment and for the discharge of the defendants and for a directed verdict of acquittal of both defendants, upon the ground that the evidence did not justify 267 a conviction, and upon the further ground that there was a reasonable doubt as a matter of law. The motions were denied and an exception reserved.

A motion was made at the conclusion of the whole case upon the same grounds as was made at the conclusion of the govern-

ment's case, which motion was denied and an exception reserved. A motion was made in due time that the notice required by Section 335 should have been given by the department to the defendant individual before prosecution, and that the proof showed that no such notice was given, and that there should be a dismissal as to the defendant individual because of the failure of the government to give such notice. This motion was denied and an exception reserved.

A motion was made for the dismissal of the defendant individual, the appellant here, Joseph H. Dotterweich, upon the ground that he was merely the general manager of the corporation, and even if the corporation did commit any offense, the offense was such as to constitute an offense mala prohibitum, and did not require any intent on the part of the corporation, and that, therefore, the employee of the corporation could certainly not be held liable for the commission of an offense committed by the corporation without intent where he had no intent to commit any crime, and further, that if a guarantee in writing to the corporation defendant could have absolved the corporation from criminal responsibility; that the defendant individual, the appellant here, could not have demanded any guarantee in writing from the seller of this merchandise; and, therefore, could not be prosecuted under this Act. That motion was denied and an exception reserved.

268 A motion was made to dismiss the indictment as against the appellant that in order to sustain a conviction of misbranding under Section 352 there must be a fraudulent intent proved. That motion was denied and an exception reserved.

A motion was made to set aside the verdict of the jury upon the ground that the verdict was against the law and against the evidence. That motion was denied and an exception reserved.

A motion was made to set aside the verdict of the jury upon the ground that the verdict was inconsistent in that the defendant corporation could not be absolved, or found not guilty, of a crime where, upon the same facts, an employee of that corporation could be found guilty, and that, therefore, that verdict was inconsistent. That motion was denied and an exception reserved.

A motion was made to set aside the verdict of the jury upon the ground that the evidence clearly indicated and showed that there was no misbranding by any false and misleading statements as charged in the informations insofar as they related to "Tablets of Cascara Compound Hinkle," first, because they were not "Pills of Cascara Compound Hinkle" as indexed and as set forth in the National Formulary, the official compendium, but that they were tablets, and that between "Pills" and "Tablets"

there is a distinctly recognized difference in the medical and pharmaceutical world, and which is clearly set forth in indexes of the National Formulary itself in designating pills and tablets of various kinds, and, second, that if there was any misbranding it was not done by the defendants but by the government, 269 in following the National Formulary referring to pills of cascara compound Hinkle, in that Hinkle's pills for a century was a formula of one Dr. Hinkle, which required strychnine sulphate as one of the important ingredients, and which was in the defendant's product, and that the government directed that strychnine sulphate shall be removed, but still retaining the name "Hinkle Pills," which in fact is not Hinkle's at all, and, therefore, is false and misleading to doctors and pharmacists, and, third, that it is not unlawful to sell cascara compound pills or tablets with strychnine sulphate in them, if clearly stated on the label, and that on the label of the defendant's product there was set forth precisely what the tablets of Cascara Compound Hinkle contained, and which is not prohibited by any regulation of the government, and fourth, that no evidence was produced to show that any doctor or that any person was misled. That motion was denied and an exception reserved.

The several motions made and denied, to which exceptions were reserved, constituted serious error.

Respectfully submitted.

ROBERT J. WHISSEL and
SAMUEL M. FLEISCHMAN,

Attorneys for Appellant,

Buffalo, N. Y.

270

In United States District Court

[Title omitted.]

Sentence

Oct. 27, 1941

This is to certify that on April 29, 1940 an information charging defendants with violation of the Federal Food, Drug & Cosmetic Act of June 25, 1938 was filed in Case No. 2104-C; that on August 5, 1940 an information charging defendant with violation of the Federal Food, Drug & Cosmetic Act of June 25, 1938 was filed in Case No. 2190-C; that on March 11, 1941 defendants were arraigned and pleaded not guilty in both cases; that on June 30, 1941 the above cases were consolidated for trial and counts 1, 2, and 3 of Information No. 2104-C were dismissed by the Court on motion of Assistant U. S. At-

torney Doran; that on July 2, 1941 the jury returned a verdict of guilty as charged in the Information against defendant Joseph H. Dotterweich, and disagreed as to the guilt of the Buffalo Pharmaceutical Company, Inc.; that on October 27, 1941 defendant Joseph H. Dotterweich was sentenced as follows: \$500.00 fine on Count 1; \$500.00 fine on Count 2; \$500.00 fine on Count 3; payment of fines on Counts 2 and 3 respectively, suspended; defendant placed on probation for sixty (60) days on each of Counts 1, 2, and 3, the period of probation on Counts 2 and 3 to run concurrently with the period of probation on Count 1. (For the purpose of this sentence, on consolidation of the cases, count 4 of Information 2104-C shall be considered Count 1 herein, and Counts 1 and 2 of Information 2190-C shall be considered Counts 2 and 3 herein.)

In testimony whereof, I have hereunto caused the seal of the aforesaid Court to be affixed at the City of Buffalo in said District this 3rd day of December 1941.

MAY C. SICKMON, Clerk.

In United States District Court

Order extending time to file to January 10, 1942

A motion having been made herein and having been duly brought on before me to be heard on November 10th, 1941, for an order extending the time within which to file a bill of exceptions and an assignment of errors in the above entitled action; and after hearing Samuel M. Fleischman, Attorney for the above named appellant, in support of said motion, and Hon. George L. Grobe, United States Attorney in and for the Western District of New York, appearing by Hon. Joseph J. Doran, Assistant United States Attorney, of counsel, and consenting thereto, and due deliberation having been had thereon, it is hereby

Ordered, that the appellant above named have sixty (60) days from the date hereof within which to file a bill of exceptions and an assignment of errors in the above entitled action.

Dated, Rochester, N. Y., November 10th, 1941.

HAROLD P. BURKE,
U. S. District Court Judge.

In United States District Court

Order extending time to file to March 20, 1942

Upon the annexed consent of the attorneys for the parties hereto, and it appearing from such consent that there is difficulty

In obtaining the minutes of the trial of the above entitled action which would be complete, and an order having been made granting time within which to file a bill of exception and an assignment of errors in the above matter, which will expire January 10th, 1942, it is hereby

Ordered, that the appellant above named have an additional sixty (60) days from said date, to wit, March 10th, 1942, within which to file a bill of exceptions and an assignment of errors in the above entitled action.

Dated New York, N. Y., December 5th, 1941.

HARRIE B. CHASE, U. S. C. J.

In United States District Court

Order extending time to file to June 19, 1942

Upon the annexed consent of the attorneys for the parties hereto, and it appearing from such consent that there is difficulty in arranging the Bill of Exceptions and Assignment of Errors in this action, due to the fact that the Assistant District Attorney who tried the case has since left his office and the stenographic minutes are in such shape as will require the attorneys to scrutinize them very carefully in order to get them in proper shape for this appeal, it is

Ordered, that the appellant above named have an additional ninety (90) days from March 10, 1942, within which to file a Bill of Exceptions and Assignment of Errors in the above entitled action.

Dated New York, N. Y., February 18, 1942.

LEARNED HAND, U. S. C. J.

274

In United States District Court

Order extending time to file to September 10, 1942

Upon the annexed consent of the attorneys for the parties hereto, and it appearing from such consent that there is difficulty in arranging the Bill of Exceptions and Assignment of Errors in this action, due to the fact that the Assistant District Attorney who tried the case has since left the office and the stenographic minutes are in such shape as will require the attorneys to scrutinize them very carefully in order to get them in proper shape for this appeal, it is

Ordered, that the appellant above named have an additional ninety (90) days from March 10, 1942, within which to file a

Bill of Exceptions and Assignment of Errors in the above entitled action.

Dated New York, N. Y., May 21st, 1942.

HYatt B. Clegg, U. S. C. J.

In United States District Court

Affidavit of no opinion

July 20, 1942

STATE OF NEW YORK.

County of Erie, City of Buffalo, ss:

275 Samuel M. Fleischman, being duly sworn, deposes and says, I was the trial counsel for the defendants in this action. There was no opinion rendered by the Hon. Harold P. Burke, Judge of the United States Court for the Western District of New York, who presided at the trial of this action, in connection with any phase of this case, except the opinion contained herein denying the motion to set aside the verdict.

SAMUEL M. FLEISCHMAN.

Sworn to before me this 20th day of July 1942.

ESTHER C. ROBERTS,
Com. of Deeds, Buffalo, N. Y.

In United States District Court

Stipulation as to exhibits

July 20, 1942

It is hereby stipulated by and between the attorneys for the respective parties to the above entitled appeal, that all exhibits contained in the Bill of Exceptions not set forth in full in the said Bill of Exceptions need not be included in the record on appeal herein, but may be used by the court and by counsel upon the argument of the appeal as if they had been fully set forth in the record on appeal.

Dated Buffalo, N. Y., July 20, 1942.

GEORGE L. GROBE,

U. S. District Attorney.

SAMUEL M. FLEISCHMAN,

Attorney for Appellant.

Judge's settlement of bill of exceptions

The Bill of Exceptions in the above-entitled proceeding contains the whole charge of the court to the jury, and contains all of the evidence involved in the rulings to which exceptions are reserved.

Settled by

HAROLD P. BURKE, Trial Judge.

In United States District Court

Stipulation as to the correctness of the record

July 20, 1942

It is hereby stipulated by and between the attorneys for the respective parties that the above and foregoing is a full, true, and correct transcript of the record in this case, and that the same may be certified by the Clerk of the District Court for the Western District of New York.

Dated Buffalo, N. Y., July 20th, 1942.

GEORGE L. GROBE,

U. S. District Attorney.

SAMUEL M. FLEISCHMAN,

Attorney for Appellant.

Certification of record

July 20, 1942

The foregoing Bill of Exceptions contains all the evidence received upon the trial of this action or relating to the foregoing exceptions, together with the exceptions to the Judge's charge, and appellant's counsel having so requested, the Trial Judge did put his signature and seal to this Bill of Exceptions this 20th day of July, 1942.

HAROLD P. BURKE,

U. S. District Judge.

[Clerk's certificate to foregoing transcript omitted in printing.]

UNITED STATES CIRCUIT COURT OF APPEALS FOR
THE SECOND CIRCUIT

No. 68—October Term, 1942

UNITED STATES OF AMERICA, COMPLAINANT-APPELLEE

BUFFALO PHARMACAL COMPANY, INC., A CORPORATION, DEFENDANT
and

JOSEPH H. DOTTERWEICH, DEFENDANT-APPELLANT

Argued October 9, 1942—Decided December 3, 1942

Appeal from the District Court of the United States for the Western District of New York.

Joseph H. Dotterweich was convicted of violating the Federal Food, Drug and Cosmetic Act, 21 U. S. C. A. § 331 (a), and has appealed from the judgment of sentence. Reversed.

Before L. HAND, SWAN, and CHASE, Circuit Judges.

Robert J. Whissel, for Appellant; Samuel M. Fleischman, of Counsel.

George L. Grobe, United States Attorney, for Appellee; Robert M. Hitchcock, Assistant U. S. Attorney, of Counsel.

SWAN, Circuit Judge: The appellant was prosecuted, together with Buffalo Pharmaceutical Company, Inc., a New York corporation of which he was general manager, for violations of section 301 (a) of the Federal Food, Drug and Cosmetic Act, 21 U. S. C. A. § 331 (a). Three counts of the informations were submitted to the jury. The first count was based on an interstate shipment on October 2, 1939, of a bottle of cascara compound which was charged to be misbranded, 21 U. S. C. A. § 352 (a); the other two counts related to an interstate shipment on January 9, 1940, of a bottle of digitalis tablets, one of the counts charging adulteration, 21 U. S. C. A. 351 (c), and the other misbranding, 21 U. S. C. A. § 352 (a). Each of the shipments was made in filling an order received through the mails by Buffalo Pharmaceutical Company from a physician resident in a state other than New York. The corporation had purchased the drugs from a wholesale manufacturer; it repackaged them for the shipments under attack. The appellant Dotterweich had no personal connection with either shipment, but he was in general charge of the corporation's business and had given general instructions to its employees to fill orders received from physicians. The jury found

him guilty on all three counts. For some unexplainable reason it disagreed as to the corporation's guilt. The sentence imposed on the appellant was a fine of \$500 on each count, with payment suspended on the second and third counts, and probation for 60 days on each count to run concurrently.

The bottle of cascara compound carried a label reading "1000 Tablets Cascara Compound * * * (Hinkle)," followed by a list of the ingredients, one of which was strychnine sulphate. The charge of misbranding was based on the fact that this ingredient had been removed from the formula for Hinkle pills, stated in the official National Formulary¹ promulgated January 1, 1939. The issue left to the jury was whether the label was false and misleading in that it would lead the purchaser or the general public to believe that the tablets contained only the ingredients designated in the official formula for Hinkle pills. Since intention to violate the statute is immaterial in a charge of misbranding,² we think the jury's finding that the label was false and misleading was not unsupported by the evidence.

The label on the bottle of digitalis tablets represented that each tablet possessed a potency of one U. S. P. unit of digitalis, whereas in fact analysis proved that the tablets were less than one-half of the represented potency. This was so far below the standard that findings of adulteration and misbranding would seem to be inevitable, unless the deterioration occurred after the bottle of tablets was shipped. It was shipped on January 9, 1940, and its contents were analyzed by government chemists in March 1940. While cross-examination brought out that digitalis tablets may deteriorate in potency by lapse of time if not properly stored, there was some testimony to indicate that the bottle in question had been properly cared for. We cannot say that the evidence was insufficient to support the verdict of adulteration and misbranding.

Section 305 of the Act, set forth in the margin,³ provides that before the Administrator reports a violation to any United States attorney for prosecution, "the person against whom such proceeding is contemplated" shall be given notice and a hearing. In the case at bar such notice was addressed only to the corporation. In response thereto the appellant appeared on behalf

¹ See 21 U. S. C. A. § 321 (j) and (n).

² See *Von Bremer v. United States*, 192 F. 904, 906 (C. C. A. 2d), *Weeks v. United States*, 224 F. 64, 68 (C. C. A. 2d) and *Strong, Cobb & Co. v. United States*, 163 F. 2d 671, 674 (C. C. A. 6) construing the Food and Drugs Act of 1906. That intention is not necessarily an element of the offense under the existing Act as made very clear by section 303, 21 U. S. C. A. § 333 (a) and (b) where different penalties are provided for simple violations and for violations "with intent to defraud or mislead."

³ 21 U. S. C. A. § 335. Hearing before report of criminal violation. Before any violation of this chapter is reported by the Administrator to any United States attorney for institution of a criminal proceeding, the person against whom such proceeding is contemplated shall be given appropriate notice and an opportunity to present his views, either orally or in writing, with regard to such contemplated proceeding.

of the corporation.¹ He contends that a notice addressed to him personally was a condition precedent to his lawful prosecution. The district judge ruled that the provision for notice and a hearing was an administrative direction to the Administrator rather than a jurisdictional requirement for criminal proceedings. We agree with this conclusion.² Such was the authoritative construction placed upon a similar provision in the Food and Drugs Act of 1906, 21 U. S. C. A. § 11. *United States v. Morgan*, 222 U. S. 274; see also *United States v. King & Howe*, 78 F. 2d 693, 696 (C. C. A. 2). In our opinion the changes in phrasology introduced by the 1938 Act are not such as to render obsolete these decisions. This appears quite clearly from the Congressional debates. 83 Cong. Rec., pp. 7792, 7791, 75th Cong., 3d sess. Articles by certain commentators are cited as expressing the opposite view,³ but we are constrained to disagree with them.

The appellant further urges that the jury's failure to convict the corporation is so inconsistent with the finding of guilt on the part of the appellant that the verdict against him cannot stand. Assuming that the statute includes within its prohibitions an agent who acts for his employer in shipping in interstate commerce misbranded or adulterated articles, the contention is without merit. No authority has been cited in support of the argument that failure to convict the principal will avoid the conviction of an agent who has committed all the elements of a crime. We think the usual principle is applicable that error cannot be asserted for inconsistency in the jury's verdict. See *Dunn v. United States*, 284 U. S. 390; *United States v. Pandolfi*, 110 F. 2d 736 (C. C. A. 2).

A more difficult question is presented by the appellant's contention that the statute is aimed only at punishment of the principal and not at punishment of an innocent agent who in good faith and in ignorance of the misbranding or adulteration takes part in an interstate shipment of food or drugs. Section 301, 21 U. S. C. A. § 331, prohibits "the following acts and the causing thereof," namely: "(a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded." Section 333 (a) of Title 21 declares that "any person" who violates any of the provisions of section 331 shall be guilty of a misdemeanor and, on conviction be subject to imprisonment or fine or both. The Act defines the term "person" to include "individual, partnership, corporation and association." 21 U. S. C. A. § 321 (e). Who is the person causing "the introduction or delivery for

¹ See "A Treatise on the Law of Food, Drugs and Cosmetics," 1942, p. 737; Law & Contemporary Problems, published by the School of Law of Duke University, 1939, Vol. 6, p. 74.

introduction" into interstate commerce of a misbranded drug? Is the clerk who innocently packs or ships it guilty of the offense, as well as the employer for whom he works? While the statutory language seems literally to include all who have any part in causing delivery for introduction into interstate commerce, there are serious objections to so construing it. Subsection (c) of 21 U. S. C. A. § 333 provides

No person shall be subject to the penalties of subsection (a) of this section * * * for having violated section 331 (a) or (d), if he establishes a guaranty or undertaking signed by, and containing the name and address of, the person residing in the United States from whom he received in good faith the article, to the effect, in the case of an alleged violation of section 331 (a), that such article is not adulterated or misbranded within the meaning of this chapter designating this chapter. * * *

Obviously such a guaranty, if given, will be obtained by the drug dealer, not by his clerk who may later deliver the article for shipment in interstate commerce; nor is such clerk literally within the protection of the quoted section, since he is not the one who "received" the article from the guarantor. It is difficult to believe that Congress expected anyone except the principal to get such a guaranty, or to make the guilt of an agent depend upon whether his employer had gotten one. The agent's guilt, like his principal's, must be independent of any scienter under section 331 (a). It would be extremely harsh to charge him criminally with the risks of the business as the drug dealer is himself charged. A majority of the court is of opinion that this cannot have been the congressional intent and that the statute must be construed to mean that only the drug dealer, whether corporation or individual, is the "person" who causes the "introduction" or "delivery for introduction" of misbranded or adulterated drugs into commerce. In support of this conclusion the appellant adverts to the omission from the present Act of a provision which appeared in the 1906 Act in 21 U. S. C. A. § 4. This declared that in construing and enforcing the provisions of sections 1 to 15 of Title 21 "the act, omission, or failure of any officer, agent or other person acting for or employed by any corporation * * * within the scope of his employment or office, shall in every case be also deemed to be the act, omission or failure of such corporation * * * as well as that of the person." In our opinion the omission of this provision adds nothing to the argument already developed; it was doubtless omitted as unnecessary because it states an obvious general principle of agency.

The foregoing discussion has proceeded upon the assumption that if the statute is applicable to the appellant it must also apply to a shipping clerk or any menial employee who was instrumental in causing the forbidden shipment, for we can find no basis in the statutory language for drawing a distinction between agents of high or low rank. We are not, however, to be understood to hold that under no circumstances could an individual conducting a drug business in corporate form be subjected to the penalties of section 331 (a). If an individual operated a corporation as his "alter ego" or agent, he might be the principal; but the evidence hardly went so far as to establish that such was the relationship between the appellant and his corporation and in any event his guilt was not made to turn on any such issue. Accordingly his conviction must be reversed.

The views above expressed in respect to the construction of the statute are those of a majority of the court. I am not in accord with them. I believe that the language of sections 331 (a) and 333 (a) is so inclusive as to render liable all persons who take part in causing a shipment in interstate commerce of misbranded or adulterated articles, and that any insufficiency in the protection afforded an agent by section 333 (c) is not an adequate reason for limiting the statutory prohibitions to the dealer. The possibility that a literal interpretation of the statute may lead to the prosecution of insignificant agents rather than their employers is not, I believe, a serious risk and is a matter Congress was willing to leave to the good sense of prosecuting officials and trial juries. See *United States v. Buffalo Cold Storage Co.*, 179 F. 865, 867 (D. C. W. D. N. Y.), where a warehouseman who innocently shipped pursuant to instructions was convicted under the 1906 Act; see also the charge given by Judge Grubb in *United States v. Mayfield*, 177 F. 765 (D. C. Ala.).

Judgment reversed.

United States Circuit Court of Appeals for the Second Circuit

THE UNITED STATES OF AMERICA, APPELLEE

v.

BUFFALO PHARMACAL COMPANY, INC., A CORPORATION, DEFENDANT

and

JOSEPH H. DOTTERWEICH, DEFENDANT-APPELLANT

Petition for rehearing, certificate, and notice

George L. Grobe, United States Attorney, Attorney for Plaintiff-Appellee, 502 U. S. Courthouse, Buffalo, New York.

Filed Dec. 29, 1942.

United States Circuit Court of Appeals for the Second Circuit

No. 68—October Term, 1942

UNITED STATES OF AMERICA, APPELLEE

v.

BUFFALO PHARMACAL COMPANY, INC., A CORPORATION, DEFENDANT

and

JOSEPH H. DOTTERWEICH, DEFENDANT-APPELLANT

NOTICE

Sir: You will please take notice that the annexed petition for rehearing, will be filed in the office of the Clerk of the United States Circuit Court of Appeals for the Second Circuit, in type-written form, on or before December 26, 1942, and that printed copies thereof will be filed with such Clerk on or before December 31, 1942, after three copies of such printed petition are served upon you.

Dated: Buffalo, New York, December 23, 1942.

Yours, etc.,

GEORGE L. GROBE,
George L. Grobe,

*United States Attorney in and for the Western District
of New York, Attorney for Plaintiff-Appellee, Office
& Post Office Address, 502 United States Courthouse,
Buffalo, New York.*

To: ROBERT J. WHISSEL, Esq.,
Attorney for Defendant-Appellant,
Liberty Bank Building, Buffalo, New York.

Copy received Dec. 23, 1942.

ROBERT J. WHISSEL,
By SAMUEL FLEISCHMAN,
Counsel, Atty. for Appellant.

Petition for rehearing

United States Circuit Court of Appeals, for the Second Circuit

No. 68—October Term, 1942

UNITED STATES OF AMERICA, APPELLEE

v.

BUFFALO PHARMACAL COMPANY, INC., A CORPORATION, DEFENDANT
and

JOSEPH H. DOTTERWEICH, DEFENDANT-APPELLANT

To the Honorable Learned Hand, Thomas W. Swan, and Harrie Brigham Chase, Judges of the United States Circuit Court of Appeals for the Second Circuit:

The petition of the United States of America, the appellee herein, by its attorney George L. Grobe, United States Attorney in and for the Western District of New York, respectfully shows to this Honorable Court and alleges:

(1) That it hereby prays for a rehearing in the above entitled matter which was argued before this Court October 9, 1942, and decided December 3, 1942, upon which date a written opinion by Honorable Thomas W. Swan, reversing the judgment of conviction herein, was filed in the office of the Clerk of this Court.

(2) That the grounds for such rehearing are as follows:

(a) In reversing the learned Court stated in part:

"It is difficult to believe that Congress expected * * * to make the guilt of an agent depend upon whether his employer had gotten one. (guaranty) * * * A majority of the court is of opinion that this cannot have been the congressional intent and that the statute must be construed to mean that only the drug dealer, whether corporation or individual, is the 'person' who causes the 'introduction' or 'delivery for introduction' of misbranded or adulterated drugs into commerce."

We believe that the learned Court in so stating failed to consider Section 550, Title 18, U. S. C., defining principals as follows:

"Whoever directly commits any act constituting an offense defined in any law of the United States, or aids, abets, counsels, commits, induces or procures its commission, is a principal."

(3) The learned Court further held that:

"We are not, however, to be understood to hold that under no circumstances could an individual conducting a drug business in corporate form be subjected to the penalties of section 331 (a). If an individual operated a corporation as his 'alter ego' or agent

he might be the principal; but the evidence hardly went so far as to establish that such was the relationship between the appellant and his corporation * * *

With respect to this holding, the learned Court failed to review the evidence establishing the intimate relationship between the individual appellant and his corporation, the co-defendant. This is reviewed beginning at the last paragraph on page 8 and ending just below the middle of page 9 of appellee's brief.

(4) We respectfully urge that it is axiomatic that a corporation can act only through agents. If a corporation is guilty of a crime, some person or persons acting for such corporation must, of necessity, be implicated, if not as principals, then assuredly as aiders and abettors.

(5) The learned Judge writing the opinion states that, "The views above expressed in respect to the construction of the statute are those of a majority of the Court. I am not in accord with them."

The learned Judge continues by stating, in substance, that in his individual opinion sections 331 (a) and 333 (a) of Title 21, U. S. C., are sufficiently inclusive as to render liable all persons who participate in causing a shipment in interstate commerce of misbranded or adulterated articles, and that any insufficiency in the protection afforded an agent by section 333 (c), Title 21, U. S. C., is no adequate reason for limiting the statutory prohibitions to the dealer. He then points out that the good sense of prosecuting officials and jurors nullifies any alarm that such interpretation may lead to the prosecution of insignificant agents, citing United States vs. Buffalo Cold Storage Co., 179 F. 865, 867, and United States vs. Mayfield, 177 F. 765, which opinions were either not considered or not embraced by Judges Hand and Chase.

(6) Appellee is not clear as to whether Judge Swan dissented from the judgment of reversal or merely from the construction of the statute. In any event, an important precedent is established in the prosecution of cases under the Federal Food, Drug and Cosmetic Act as so many such prosecutions involve "one man" corporations and effective and adequate prosecution requires the naming as defendants of all involved. If the sole stockholder, sole manager, who admits his responsibility for the occurrences charged in the information, cannot be successfully prosecuted, we believe that this Court, in so holding, should define the place of vulnerability where the shield of the corporate fiction no longer protects him.

Wherefore, your petitioner respectfully prays that a rehearing be ordered herein and that counsel be allowed to argue and brief

the points raised hereinabove, and further prays that the mandate of this Court be stayed pending the determination of this petition, and for such other, further and different relief as to the Court may seem just in the premises.

UNITED STATES OF AMERICA.

Plaintiff-Appellee.

S. GEORGE L. GROBE.

By George L. Grobe.

United States Attorney in and for the Western District of New York, its attorney, Office & Post Office Address, 502 United States Courthouse, Buffalo, New York.

STATE OF NEW YORK AND WESTERN DISTRICT OF NEW YORK.

County of Erie, City of Buffalo, ss.

GEORGE L. GROBE, being duly sworn, deposes and says that he is an United States Attorney in and for the Western District of New York, and is attorney for the petitioner herein; that he has read the foregoing petition and knows the contents thereof; that the same is true to his own knowledge except as to the matters therein stated to be alleged upon information and belief and that as to those matters he believes it to be true.

That the reason this petition is verified by deponent rather than petitioner is that petitioner is a sovereign corporation.

S. GEORGE L. GROBE.

Sworn to before me this 23rd day of December, 1942.

S. MARGARET D. HAZEL.

Notary Public, Erie County, N. Y.

Certificate

United States Circuit Court of Appeals for the Second Circuit

No. 68—October Term, 1942

UNITED STATES OF AMERICA, APPELLEE.

BUFFALO PHARMACAL COMPANY, INC., A CORPORATION, DEFENDANT
and

JOSEPH H. DOTTERWEICH, DEFENDANT-APPELLANT

The undersigned hereby certifies that he is the attorney for the plaintiff-appellee herein and that he is authorized and directed by the appellee, the United States of America, to make this petition for a rehearing of the issues raised in the appeal herein. That the same is made in good faith and in the belief

that this Court has overlooked and failed to understand material issues of law and fact herein.

Dated: Buffalo, New York, December 23, 1942.

S/ **GEORGE L. GROBE**

*United States Attorney in and for
the Western District of New York.*

United States Circuit Court of Appeals for the Second Circuit

THE UNITED STATES OF AMERICA, COMPLAINANT-APPELLEE

BUFFALO PHARMACAL COMPANY, INC., A CORPORATION, DEFENDANT
and

JOSEPH H. DOTTERWEICH, DEFENDANT-APPELLANT

Before **L. HAND, SWAN, and CHASE, Circuit Judges**

Petition for a hearing

George L. Grobe, United States Attorney, for Appellee.

PER CURIAM:

Petition for rehearing is denied. Our mandate will reverse the judgment and remand the cause for a new trial on the issue not submitted to the jury on the prior trial, but alluded to in our opinion, namely, whether the appellant operated the corporation as his "alter ego" or agent.

L. H.

T. W. S.

H. B. C.

C. J. J.

United States Circuit Court of Appeals for the Second Circuit

At a Stated Term of the United States Circuit Court of Appeals, in and for the Second Circuit, held at the United States Courthouse in the City of New York, on the 4th day of January one thousand nine hundred and forty-three.

Present: Hon. LEARNED HAND, Hon. THOMAS W. SWAN, Hon. HARRIE B. CHASE, Circuit Judges.

THE UNITED STATES OF AMERICA, COMPLAINANT-APPELLEE

v.

BUFFALO PHARMACAL COMPANY, INC., A CORPORATION, DEFENDANT
and

JOSEPH H. DOTTERWEICH, DEFENDANT-APPELLANT

A petition for a rehearing having been filed herein by counsel for the Appellee.

Upon consideration thereof, it is,

Ordered that said petition be and hereby is denied.

Further ordered that the mandate of this Court reverse the judgment and remand the cause for a new trial on the issue not submitted to the jury on the prior trial, but alluded to in the opinion of this Court, namely, whether the appellant operated the corporation as his "alter ego" or agent.

D. E. ROBERTS, Clerk.

Order

United States Circuit Court of Appeals, Second Circuit. Filed Jan. 4, 1943. D. E. Roberts, clerk.

United States Circuit Court of Appeals for the Second Circuit

At a stated Term of the United States Circuit Court of Appeals, in and for the Second Circuit, held at the United States Courthouse in the City of New York, on the 4th day of January, one thousand nine hundred and forty-three.

Present: Hon. LEARNED HAND, Hon. THOMAS W. SWAN, Hon. HARRIE B. CHASE, Circuit Judges.

UNITED STATES OF AMERICA, PLAINTIFF-APPELLEE

v.

BUFFALO PHARMACAL COMPANY, INC., A CORPORATION, DEFENDANT
and

JOSEPH H. DOTTERWEICH, DEFENDANT-APPELLANT

Appeal from the District Court of the United States for the Western District of New York.

This cause came on to be heard on the transcript of record from the District Court of the United States for the Western District of New York and was argued by counsel.

On consideration, whereof, it is now hereby ordered, adjudged, and decreed that the judgment of said District Court be and it

hereby is reversed, and cause remanded for a new trial on the issue not submitted to the jury on the prior trial, but alluded to in the opinion of this Court, namely, whether the appellant operated the corporation as his "alter ego" or agent.

It is further ordered that a mandate issue to the said District Court in accordance with this decree.

D. E. ROBERTS, Clerk.

ORDER FOR MANDATE.

United States Circuit Court of Appeals, Second Circuit.
Filed Jan. 4, 1943. D. E. Roberts, clerk.

United States of America, Southern District of New York

I, D. E. Roberts, Clerk of the United States Circuit Court of Appeals for the Second Circuit, do hereby certify that the foregoing pages, numbered from 1 to 298, inclusive, contain a true and complete transcript of the record and proceedings had in said Court, in the case of United States of America, Plaintiff-Appellee, against Buffalo Pharmacal Company, Inc., a corporation, Defendant, and Joseph H. Dotterweich, Defendant-Appellant, as the same remain of record and on file in my office.

In testimony whereof, I have caused the seal of the said Court to be hereunto affixed, at the City of New York, in the Southern District of New York, in the Second Circuit, this third day of February in the year of our Lord one thousand nine hundred and forty-three, and of the Independence of the said United States the one hundred and sixty-seventh.

[SEAL]

D. E. ROBERTS, Clerk.

Supreme Court of the United States

No. 717. October Term, 1942

[Title omitted.]

Order allowing certiorari

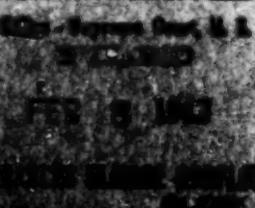
Filed April 5, 1943

The petition herein for a writ of certiorari to the United States Circuit Court of Appeals for the Second Circuit is granted.

And it is further ordered that the duly certified copy of the transcript of the proceedings below, which accompanied the petition, shall be treated as though filed in response to such writ.

[Endorsement on cover:] File No. 47218. U. S. Circuit Court of Appeals, Second Circuit. Term No. 717. The United States of America, Petitioner, vs. Joseph H. Dotterweich. Petition for a writ of certiorari and exhibit thereto. Filed February 8, 1943. Term No. 717 O. T. 1942.

RECORDED



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(1)

In the Supreme Court of the United States

OCTOBER TERM, 1942

No. 717

THE UNITED STATES OF AMERICA, PETITIONER
v.

JOSEPH H. DOTTERWEICH

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES CIRCUIT COURT OF APPEALS FOR THE SECOND CIRCUIT

The Solicitor General, on behalf of the United States, prays that a writ of certiorari issue to review the judgment of the United States Circuit Court of Appeals for the Second Circuit, entered December 3, 1942 (R. 282), setting aside a conviction for violations of the Federal Food, Drug, and Cosmetic Act of 1938.

OPINION BELOW

The opinion of the Circuit Court of Appeals (R. 278-282) is reported in 131 F. (2d) 500.

JURISDICTION

The judgment of the Circuit Court of Appeals was entered on December 3, 1942, and petition for

rehearing was denied on January 4, 1943 (R. 287). The jurisdiction of this Court is invoked under Section 240 (a) of the Judicial Code, as amended by the Act of February 13, 1925.

QUESTION PRESENTED

Whether the manager of a corporation, as well as the corporation itself, may be prosecuted under the Federal Food, Drug, and Cosmetic Act of 1938 for the introduction of misbranded and adulterated articles into interstate commerce.

STATUTE INVOLVED

The pertinent provisions of the Federal Food, Drug, and Cosmetic Act of 1938, 52 Stat. 1040 (21 U. S. C., secs. 321-381), are printed in Appendix A, *infra*, pp. 12-14.

STATEMENT

On April 29 and August 15, 1940, informations were filed in the District Court for the Western District of New York, naming as defendants Buffalo Pharmacal Company, Inc., a corporation, and respondent Joseph H. Dotterweich, alleging violations of Section 301 (a) of the Federal Food, Drug, and Cosmetic Act through introduction of misbranded and adulterated drugs into interstate commerce, and delivery of such goods for such introduction (R. 3-11). The two informations were consolidated for trial, and three counts were submitted to the jury (R. 20, 21, 23). The jury

disagreed as to the corporation but convicted respondent Dotterweich on all three counts (R. 23). On October 27, 1941, he was sentenced to a five-hundred dollar fine on each count, but payment was suspended as to all but one count, and he was placed on sixty days' probation (R. 24, 270-271.)

The pertinent counts of the information charged the introduction and delivery for introduction in interstate commerce of (1) a bottle of misbranded cascara compound, on or about October 2, 1939; (2) a bottle of adulterated digitalis tablets, on or about January 9, 1940; and (3) a bottle of misbranded digitalis tablets, on or about January 9, 1940.

The evidence of misbranding in Count I was that the bottle bore a label reading, "1,000 tablets, cascara compound . . . (Hinkle)", followed by a list of ingredients, one of which was strychnine sulphate, but that at the time of shipment of the drug this formula was obsolete, since the then current revision of the official National Formulary, the statutory standard, Section 201 (j), Section 501 (b), omitted strychnine sulphate from the Hinkle formula (R. 16-17, 63-64). The evidence of misbranding and adulteration of the bottle of digitalis tablets under Counts II and III was that its label represented that each tablet possessed a potency of 1 U. S. P. unit of digitalis, although in fact the tablets were of less than one-half the pur-

ported potency, in violation of Sections 501 (e) and 502 (a) (R. 34, 81).¹

The corporation was not itself a manufacturer of drugs, but a "jobber," purchasing its drugs from manufacturers, and had sold the drugs in question in interstate commerce after repackaging them under its own label (R. 27-28, 46, 197; 12, 16-17, 186-187). The individual defendant, respondent Dotterweich, was the corporation's general manager (R. 47, 58, 223). He had not himself packed or shipped the drugs, but was in general charge of the corporation's operations, the packaging and shipping having been carried out in accordance with his general instructions (R. 223-225). The court instructed the jury that his guilt required a finding that he was "responsible" for the shipments, that is, that they were made "under his supervision" "as General Manager" (R. 257).

The court below, while rejecting other contentions of the respondent, reversed the conviction on the ground that the criminal provisions of the Act were not aimed at employees but solely at nominal principals.² In reversing and remanding for new trial, the court directed that there be submitted to the jury the issue whether the appellant operated

¹ The court below held that the findings of misbranding as to the first count, and of adulteration and misbranding as to the second and third counts, were supported by the evidence (R. 279).

² The phrase is used here to avoid confusion with the definition of principal in the Criminal Code, *infra*, p. 8, n. 5, which we deem applicable.

the corporation as his "alter ego" or agent. Judge Swan, who wrote the opinion, dissented on this issue of statutory construction.

SPECIFICATION OF ERRORS TO BE URGED

The Circuit Court of Appeals erred:

1. In construing the criminal provisions of the Federal Food, Drug, and Cosmetic Act of 1938 as not applicable to a responsible corporate officer such as respondent.
2. In reversing the judgment of conviction.

REASONS FOR GRANTING THE WRIT

The court below recognized that the criminal provisions of Section 303 (a) of the Act apply to "any person" who violates the prohibitions of the Act, and that criminal liability for the introduction of misbranded or adulterated goods into interstate commerce, which is prohibited by Section 301 (a), does not turn on want of good faith. Indeed, bad faith under the Act operates to increase the severity of the punishment. Section 303 (b). The majority below were influenced by their construction and oblique application of the immunity provision in Section 303 (e) (2), which provides that no "person" shall be subject to liability for violation of Section 301 (a) if he establishes a guaranty from the person "from whom he received in good faith the article." Construing this provision to confer immunity only on the "receiver" of the guaranty, and deeming the corporation to be the

receiver, the majority concluded that only the corporation could be liable in the present case.

In so holding, the court has rendered a decision of major importance in the enforcement of the Act, and one which overturns an administrative and judicial construction of long standing.

1. Since July 1, 1939, the earliest effective date of any of the provisions of the 1938 Act,³ the Food and Drug Administration has initiated approximately 1,000 criminal cases. In the calendar year ended December 31, 1942, there were more than four hundred such cases. About one-half of these (208) involved corporate defendants, and in approximately 30 percent (61) one or more officers and employees of a corporation were joined as defendants. It has been the policy of the Food and Drug Administration, as a matter of administrative discretion, to avoid prosecution of mere underlings acting under instructions. The administration has held itself precluded from prosecuting even responsible officers and employees if the corporation holds a guaranty. The instant case serves as illustration. There is no suggestion of a guaranty here. The workmen who performed the actual operations of bottling, labeling and shipping were not named as defendants. Enforcement practice has recognized the fact that the statute, since

³ Some of the provisions of the statute did not become effective at once, Section 902 (a); see also Act of June 23, 1939, c. 242, 53 Stat. 852, Section 1.

it imposes criminal liability for acts dangerous to the public even when committed without intent to harm, has as its aim the inculeation of an attitude of vigilant care on the part of the industries affected.⁴ Accordingly, the individual defendants named in criminal prosecutions have tended to be persons such as respondent Dotterweich, persons with policy-making and discretionary functions quite apart from whether or not they control the whole enterprise, since it is those persons who have the power to initiate precautionary measures to avoid violation of the Act.

While the seizure provisions of Section 304 are unaffected by the instant decision, since they operate against the goods themselves and not against "persons," recourse to seizure is inadequate to remove adulterated or misbranded goods from the market without enforcement by an impracticably large investigative staff. Ordinarily, and particularly in the case of large corporations, the persons penalized by seizures or by the assessment of fines against the corporation are the stockholders, who may not even be aware of the penalty. Unless the individuals who actually carry on the business can be named as defendants, these persons gain immunity by reason of the corporate form, for the monetary loss through seizure or through fine imposed upon the corporation often operates merely as a

⁴ See *United States v. Balint*, 258 U. S. 250, 252.

license fee to carry on the business in an illegal manner. It is the combined effect of the criminal, injunction, and seizure methods which gives the statute its present effectiveness in protecting the public from articles dangerous to health. Enforcement has therefore frequently proceeded directly against managerial personnel, taking the view that the prospect of jail sentence in a criminal case or in a contempt proceeding for violation of an injunction decree is the most effective deterrent.

2. The existing administrative practice, contemplating enforcement against responsible agents, officers, and employees who are above the level of mere hired hands, is a continuation of over thirty years' enforcement policy under the predecessor Act of 1906. Prosecutions of individuals have never been restricted to those who dominate the enterprise but have included persons with varying but substantial degrees of discretionary responsibility. The suggestion that criminal liability under the 1906 Act was restricted to nominal principals, individual or corporate, was repeatedly rejected by the courts in the early years of operation under that Act, and apparently never since raised. *United States v. Mayfield*, 177 Fed. 765 (N. D. Ala.); *United States v. Buffalo Cold Storage Co.*, 179 Fed. 865 (W. D. N. Y.); *United States v. Kellett* (D. Utah), reported in White and Gates,

Decisions of Courts in Cases under the Federal Food and Drugs Act (1934), pp. 711, 713.

The 1906 Act likewise contained a guaranty provision in which there was implicit the very issue which the court below considered. Section 9, 34 Stat. 771, exempted a dealer from prosecution "when he can establish a guaranty signed by the wholesaler, jobber, manufacturer, or other party residing in the United States, *from whom he purchases* such articles * * *." [Italics supplied]. Thus under that Act, too, an argument was possible that the privilege of acquiring the guaranty immunity was restricted literally to those who purchase, i. e., to the principals, and that hence liability was also restricted to principals. Such an argument never found acceptance.

The practice of not prosecuting even responsible officials if the corporation holds a guaranty has

⁵ Section 12 of the Act of June 30, 1906, c. 3915, 34 Stat. 768, 772, provided that "the act, omission, or failure of any officer, agent, or other person acting for or employed by any corporation, company, society, or association, within the scope of his employment or office, shall in every case be also deemed to be the act, omission, or failure of such corporation, company, society, or association as well as that of the person." The Act anticipated the general provision in the Criminal Code defining principals (Act of Mar. 4, 1909, c. 321, sec. 332, 35 Stat. 1152, 18 U. S. C. sec. 550): "Whoever directly commits any act constituting an offense defined in any law of the United States, or aids, abets, counsels, commands, induces, or procures its commission, is a principal."

been regarded by the Food and Drug Administration not as an exercise of discretion but as a conformance to statutory requirement. In the *Mayfield* case, *supra*, the court made clear that only because the corporation could not establish a guaranty were the officers subject to prosecution under the Act of 1906. See also *Turner v. State*, 171 Tenn. 36, 100 S. W. (2d) 236. In short, the guaranty has been treated as one running with the goods, for the purpose of allowing relaxation of vigilance where another person, in a position to exercise all necessary vigilance, is willing to assert that he has done so, for that person has thereby subjected himself under Section 301 (h) to prosecution should his guaranty be factually false.⁶

⁶ The construction by the court below of the guaranty provision in Section 303 (c) (2) leads to anomalous results. The next subsection, 303 (c) (3), relating to adulteration by use of uncertified coal-tar color, likewise contains a guaranty provision protecting "any person," but it does not mention the matter of "receiving" the articles. It is hardly to be supposed that Congress intended the scope of this guaranty and of criminal liability to be broader than under Section 303 (c) (2). The introduction of new drugs without certification is a violation of Section 301, as is the offense charged in the instant case; and Section 303 (c) (2) is likewise the relevant immunity provision. Under the lower court's construction, a manager could claim immunity under a guaranty in the case of coal-tar colors, and so presumably could be prosecuted in the absence of a guaranty, but not so in the case of new drugs, which might themselves be coal-tar products. This anomaly is avoided by treating the statute, in accordance with the administrative construction, as protecting any person who handles the goods on behalf of his principal.

CONCLUSION

3. Thirty-one state statutes contain provisions comparable to those in the instant case.¹ The decision below is thus likely to have an importance beyond its technical confines.

For the foregoing reasons it is respectfully submitted that this petition for a writ of certiorari should be granted.

CHARLES FAHY,
Solicitor General.

FEBRUARY 1943.

¹ The state statutes are listed in Appendix B, *infra*, pp. 15-17. Under these statutes, there is likewise criminal liability for unintentional violation, and employees are not exempted by the mere existence of guaranty provisions. See: *Turner v. State*, 171 Tenn. 36, 100 S. W. (2d) 236; *People v. Schwartz*, 28 Cal. App. 775, 70 Pac. (2d) 1017; see also *Commonwealth v. Lutz*, 137 Pa. Sup. 449, 9 At. (2d) 481.

APPENDIX A

The Federal Food, Drug, and Cosmetic Act of 1938, 52 Stat. 1040, in pertinent part provides as follows:

SEC. 201. For the purposes of this Act—

(e) The term "person" includes individual, partnership, corporation, and association. (21 U. S. C. 321 (e).)

SEC. 301. The following acts and the causing thereof are hereby prohibited:

(a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded.

(h) The giving of a guaranty or undertaking referred to in section 303 (c) (2), which guaranty or undertaking is false, except by a person who relied upon a guaranty or undertaking to the same effect signed by, and containing the name and address of, the person residing in the United States from whom he received in good faith the food, drug, device, or cosmetic; or the giving of a guaranty or undertaking referred to in section 303 (c) (3), which guaranty or undertaking is false. (21 U. S. C. 331 (a) (h).)

SEC. 303. (a) Any person who violates any of the provisions of section 301 shall be guilty of a misdemeanor and shall on con-

violation thereof be subject to imprisonment for not more than one year, or a fine of not more than \$1,000, or both such imprisonment and fine; but if the violation is committed after a conviction of such person under this section has become final such person shall be subject to imprisonment for not more than three years, or a fine of not more than \$10,000, or both such imprisonment and fine.

(b) Notwithstanding the provisions of subsection (a) of this section, in case of a violation of any of the provisions of section 301, with intent to defraud or mislead, the penalty shall be imprisonment for not more than three years, or fine of not more than \$10,000, or both such imprisonment and fine.

(c) No person shall be subject to the penalties of subsection (a) of this section, * * * (2) for having violated section 301 (a) or (d), if he establishes a guaranty or undertaking signed by, and containing the name and address of, the person residing in the United States from whom he received in good faith the article, to the effect, in case of an alleged violation of section 301 (a), that such article is not adulterated or misbranded, within the meaning of this Act, designating this Act, or to the effect, in case of an alleged violation of section 301 (d), that such article is not an article which may not, under the provisions of section 404 or 505, be introduced into interstate commerce; or (3) for having violated section 301 (a), where the violation exists because the article is adulterated by reason of containing a coal-tar color not from a batch certified in accordance with regulations promulgated by the Secretary under this Act if such person establishes a guaranty or undertaking

signed by, and containing the name and address of, the manufacturer of the coal-tar color, to the effect that such color was from a batch certified in accordance with the applicable regulations promulgated by the Secretary under this Act. (21 U. S. C. 333.)

APPENDIX B

The Food and Drug Laws of the following States contain coverage and guaranty provisions which are substantially the same as those of the Federal Food and Drugs Act of 1906 and the Federal Food, Drug, and Cosmetic Act of 1938:

1. Alabama—Code of Alabama, 1940. Title 2, Sections 1 and 331.
2. Arizona—Code Annotated, 1939. Sec. 68-410, Sec. 68-412.
3. Arkansas—Part 1 of Ch. 70 of Pope's Digest, as amended by Act 10.190, Reg. Sess. of 1939. Sec. 6008, Sec. 6015.
4. California—Ch. 3 of Div. XXI of Health and Safety Code, added by Ch. 731, Laws of 1939; amended by ch. 1042, 1147, 1149, Laws of 1941. Sec. 26511, Sec. 26520.
5. Colorado—Statutes Annotated, 1935. Ch. 69, Sections 2, 9, 11.
6. Connecticut—Sec. 886e-919e of Ch. 135b of 1939 Supp. to General Statutes. Ch. 364, Laws of 1939 as amended by House Bill 2693, effective 1941, Sec. 3 (e), Sec. 6 (e).
7. Florida—Ch. 19656 (No. 661), Laws of 1939, Sec. 2 (b), Sec. 5 (b).
8. Georgia—Code Annotated, Sec. 42-108, Sec. 42-115, Sec. 42-9901.
9. Idaho—Code Annotated, 1932, Sec. 36-302, Sec. 36-311, Sec. 36-313.

10. Indiana—Burns Indiana Statutes Annotated, Sec. 35-1230 (e), Sec. 35-1233 (c).
11. Kansas—General Statutes Annotated, Sec. 65-602, Sec. 65-609, Sec. 65-610.
12. Kentucky—Revised Statutes, 1942, Sec. 217.060, Sec. 217.160, Sec. 217.990.
13. Louisiana—Act No. 142, Acts of 1936, amended by Act No. 185, Acts of 1942. Sec. 2 (e), Sec. 20 (d).
14. Maryland—Flack's Annotated Code, 1939, Art. 43, Sec. 189 and Sec. 193.
15. Massachusetts—Annotated Laws, Ch. 94, Sec. 191 and Sec. 193.
16. Michigan—Statutes Annotated, Title 14, Sec. 14.787 and Sec. 14.781.
17. Missouri—Statutes Annotated, Art. 2, Sec. 13027, Sec. 13028, Sec. 13029.
18. Montana—Revised Code, 1935. Ch. 237, Sec. 2578 and Sec. 2588.
19. Nebraska—Compiled Statutes, 1929, Sec. 81-908, Sec. 81-910, Sec. 81-911.
20. New Jersey—Statutes Annotated, Sec. 24:5-2, Sec. 24:1-3, Sec. 24:17-1.
21. New York—McKinney's Consolidated Laws, Art. 17, Bk. 2B, Sec. 198.2, Sec. 214.
22. North Carolina—S. Bill No. 232, Reg. Sess. 1939, Sec. 2 (b), Sec. 5 (b).
23. Oklahoma—Oklahoma Statutes, 1941, Title 63, Sec. 182 and Sec. 260.
24. Pennsylvania—Compiled Statutes (Purdon's), 1936, Title 31, Sec. 2 and Sec. 5.
25. Rhode Island—General Laws, 1938, Ch. 269, Ch. 1 and Ch. 7.
26. South Carolina—Code, 1942, Sec. 5128-27 (1) and (5).
27. South Dakota—Code, 1939, Sec. 22.0404, Sec. 22.0407, Sec. 22.9905.

28. Tennessee—Ch. 120, S. 568, 1941, Sec. 2 (b) and Sec. 5 (b).
29. Virginia—S. Bill 310, Reg. Sess. 1940, Sec. 2 (b) and Sec. 5 (b).
30. Washington—Pierce's Code, 1929, Sec. 2535 and Sec. 2539.
31. Wyoming—Revised Statutes 1931, Supp. 1940, Sec. 45-117, Sec. 45-118.

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In the Supreme Court of the United States

OCTOBER TERM, 1943

No. 5

THE UNITED STATES OF AMERICA, PETITIONER

v.

JOSEPH H. DOTTERWEICH

ON WRIT OF CERTIORARI TO THE UNITED STATES CIRCUIT
COURT OF APPEALS FOR THE SECOND CIRCUIT

BRIEF FOR THE UNITED STATES

OPINION BELOW

The opinion of the circuit court of appeals (R. 177-181) is reported at 131 F. (2d) 500.

JURISDICTION

The judgment of the circuit court of appeals was entered December 3, 1942 (see R. 177), and a petition for rehearing was denied January 4, 1943 (R. 186, 187).¹ The petition for a writ of

¹ The original judgment was one of reversal without mention of a new trial (R. 181). On denial of the motion for rehearing the court ordered that the cause be remanded for a new trial "on the issue not submitted to the jury on the prior trial, but alluded to in the opinion of this Court, namely, whether the appellant [respondent here] operated the corporation as his 'alter ego' or agent" (R. 186, 187).

certiorari was filed February 8, 1943, and granted April 5, 1943 (R. 189). The jurisdiction of this Court rests on Section 240 (a) of the Judicial Code, as amended by the Act of February 13, 1925.

QUESTION PRESENTED

Whether the manager of a corporation, having general supervision of its business consisting of the packaging, sale, and shipment of drugs, may be prosecuted under the Federal Food, Drug, and Cosmetic Act of 1938 for the introduction, in the course of the corporate business, of misbranded and adulterated drugs into interstate commerce.

STATUTE INVOLVED

The pertinent portions of the Federal Food, Drug, and Cosmetic Act of 1938, 52 Stat. 1040, 21 U. S. C., Sec. 301, *et seq.*, are set forth in Appendix A, *infra*, pp. 35-36.

STATEMENT

On April 29 and August 5, 1940, informations were filed in the District Court for the Western District of New York, charging violations by Buffalo Pharmacal Company, Inc., a corporation, and respondent Joseph H. Dotterweich of section 301 (a) of the Federal Food, Drug, and Cosmetic Act, through the introduction and delivery for introduction into interstate commerce of misbranded and adulterated drugs (R. 2-7). The two informations were consolidated for trial, and

three counts were submitted to the jury (R. 1, 13-14, 160, 165), which disagreed as to the corporation but convicted respondent Dotterweich on all three counts (R. 1, 15, 173). On October 27, 1941, he was sentenced to a five-hundred-dollar fine on each count, with payment suspended under all but one count, and he was placed on sixty days' probation (R. 2, 15, 173).

The counts on which respondent was convicted charged him with the introduction and delivery for introduction into interstate commerce of (1) a bottle of misbranded cascara compound, on or about October 2, 1939 (R. 1, 4);² (2) a bottle of adulterated digitalis tablets, on or about January 8, 1940 (R. 1, 5-6); and (3) a bottle of misbranded digitalis tablets, on or about January 8, 1940 (R. 1, 6-7).³

The evidence of misbranding under the first count was that the bottle bore a label reading "1,000 tablets, cascara compound * * * (Hinkle)," followed by a list of ingredients one of which was strychnine sulphate, whereas at the time of shipment the then current revision of the official National Formulary, which was the statutory standard under sections 201 (j) and 502 (g) of

² A count of the information (R. 2-3) which was dismissed (R. 1) charged that the cascara was also adulterated.

³ The same bottle of digitalis tablets was the subject of both the adulteration count and the misbranding count. The facts constituting the interstate character of the commerce were stipulated (R. 7-12).

the Act,² omitted strychnine sulphate from the Hinkle formula (R. 26, 27, 40-41, 45-47). The evidence of adulteration and misbranding of the bottle of digitalis tablets was that, in violation of sections 501 (b) and 502 (a) of the Act, the tablets were of less than half the potency of 1 U. S. P. unit of digitalis per tablet, which the United States Pharmacopœia called for and which the label on the bottle represented them to have (R. 52, 56, 59, 77, 98).³ The court below held that the findings of misbranding under the first count, and

⁴ Section 502 (g) (21 U. S. C. 352 (g)) provides that a drug shall be deemed misbranded "If it purports to be a drug the name of which is recognized in an official compendium, unless it is packaged and labeled as prescribed therein"; and section 201 (j) (21 U. S. C. 321 (j)) provides that "The term 'official compendium' means the official United States Pharmacopœia, official Homeopathic Pharmacopœia of the United States, official National Formulary, or any supplement to any of them." The "Hinkle formula" is contained in the National Formulary (R. 40, 110), which therefore is the statutory standard for determining whether tablets, sold by the name "Hinkle" are misbranded. The information (R. 4) and the charge to the jury (R. 160, 161) both proceeded on the theory that the cascara was misbranded only if its label was false and misleading, as proscribed by section 502 (a) (21 U. S. C. Sec. 352 (a)), and the conviction was on that ground.

⁵ Section 501 (b) (21 U. S. C. 351 (b)) provides that a drug shall be deemed adulterated "If it purports to be or is represented as a drug the name of which is recognized in an official compendium, and its strength differs from, or its quality or purity falls below, the standard set forth in such compendium." Digitalis is a drug recognized in the United States Pharmacopœia (R. 71-73, 77), which therefore is the statutory standard. Since the label on the bottle of digitalis tablets here involved represented them to have the

of adulteration and misbranding under the second and third counts, were sustained by the evidence (R. 178).⁵

The corporation was not a manufacturer of drugs, but a jobber purchasing from manufacturers (R. 17, 19, 30, 126), and had shipped the drugs in question in interstate commerce after repackaging them under its own label (R. 7-12). Respondent was the corporation's president and

content and strength called for by the United States Pharmacopoeia, there was no misbranding under section 502 (g); but since they did not in fact possess such strength, there was a misbranding under section 502 (a) (21 U. S. C. 352 (a)), which provides that a drug shall be deemed misbranded "If its labeling is false or misleading in any particular."

The defense under the second and third counts was weaker than the opinion below makes it appear. There was no evidence that digitalis tablets would deteriorate under the conditions under which they were kept (R. 59-60, 64-65) and the evidence was not clear that they would deteriorate at all short of being cooked or liquefied (R. 55-56, 65, 87-89, 90, 100-101, 146) since the causes of deterioration have not been established (R. 56, 88, 89, 100). However, assuming that the tablets would lose potency with time, the evidence also showed a greater lapse of time between manufacture of the tablets and their sale by defendants than between sale by defendants and analysis by the government. The tablets were completed by Arner and Co. on February 3, 1939 (R. 145), were shipped to defendants in five lots between March 2, 1939, and October 13, 1939 (R. 128-129), were sold by defendant corporation about January 8, 1940 (R. 59), and assayed by government pharmacologists on March 4, 9-11, 1940 (R. 50, 74). Also, Arner and Co. did not test the potency of these tablets before shipping them to defendant corporation (R. 135), and no evidence, which would have been crucial if available, was presented that defendants tested them or the batch from which they came at any time before selling them.

general manager (R. 30, 35, 37, 143-145). He had not personally packed or shipped the drugs in question, but was in general charge of the corporation's operations and the packaging and shipping were carried out in accordance with his general instructions (R. 30-31, 143-144). He himself had worked out and established the method by which the corporation operated (R. 129). On the days that these drugs were shipped, he was the person having supervision over all employees (R. 35, 143). The court instructed the jury that for it to find him guilty required a finding that he was "responsible" for the shipments, that is, that they were made under his "supervision" as "General Manager" (R. 164).

Although rejecting all other grounds urged by respondent⁷ the court below reversed his conviction on the ground that the criminal provisions of the Act were aimed not at employees but solely at nominal principals.⁸ It held that "the stat-

⁷ Respondent contended that the evidence did not sustain the charges of adulteration and misbranding, that by virtue of section 305 of the Act (21 U. S. C., sec. 335) a prosecution could not be maintained without his having first been given a hearing before the Administrator, and that the jury's failure to convict the corporation was so inconsistent with his own guilt that the verdict against him could not be allowed to stand (R. 168-172). The opinion of the court below disposes of these contentions (R. 178-179).

⁸ The phrase "nominal principals" is used to avoid confusion with definition of a "principal" contained in section 332 of the Criminal Code (Act of Mar. 4, 1909, c. 321, Sec. 332, 35 Stat. 1152, 48 U. S. C., Sec. 550).

ute must be construed to mean that only the drug dealer, whether corporation or individual, is the 'person' who causes the 'introduction' or 'delivery for introduction' of misbranded or adulterated drugs into commerce" (R. 180), and that where the "dealer" is a corporation, an individual connected therewith may be held personally only if he is operating the corporation "as his 'alter ego' or agent," so that *he* is *its* principal (R. 181, 186, 187). The court relied upon section 303 (e) of the Act, which extends immunity from the penalties provided by section 303 (a) to a person who can establish a guaranty "signed by, and containing the name and address of, the person residing in the United States *from whom he received* in good faith the article." [Italics supplied.] The court reasoned that since it is the drug dealer—in this case the corporation—that "receives" the goods and would receive the guaranty, if given, the protection of section 303 (e) would extend only to such dealer and not to his employees; that Congress could not have intended to make the employee's guilt depend upon whether his employer had received such a guaranty; that it would be extremely harsh to charge the innocent employee criminally with the risks of the business as the drug dealer himself is charged; and that there is no basis in the statute "for drawing a distinction between agents of high or low rank" (R. 180-181). Judge Swan, who wrote the opinion, dis-

sented from the majority's construction of the Act (R. 181). In reversing and remanding the case for a new trial, the court directed that there be submitted to the jury the issue of whether respondent operated the corporation as his "alter ego" or agent (R. 186, 187).

SPECIFICATION OF ERRORS TO BE URGED

The circuit court of appeals erred:

1. In construing the criminal provisions of the Federal Food, Drug, and Cosmetic Act of 1938 as not applicable to a responsible corporate officer such as respondent.
2. In reversing the judgment of conviction.

SUMMARY OF ARGUMENT

A. The construction adopted below is, as the court itself recognized, contrary to the literal meaning of the Act, which penalizes every "person" introducing nonconforming products into interstate commerce. That construction proceeded from the views that the guaranty and immunity provision in clause (2) of section 303 (e) protected only the principal and that Congress intended the penal provisions to be limited by the guaranty provisions. No indication exists, however, that Congress desired the guaranty provisions to control the scope of the penal provisions. In any event the court misinterpreted the scope of the guaranty, which issues to the dealer from the "person" from whom he "receives" the

goods: the purpose of the word "receives" is not to restrict the class protected by the guaranty but to enlarge the class which can issue it, in contrast to the guaranty authorized by clause (3) of section 303 (c) which can be issued only by the manufacturer. Also, the anomalous results which can flow from limiting the protection of a clause (2) guaranty to one who in a narrow sense "receives" it, whereas the protection afforded by a clause (3) guaranty is not so limited, argue against the interpretation adopted below.

Furthermore, the construction below is erroneous because its effect would be to render the individual agent of the corporation immune from penal liability even if he did a proscribed act with intent "to defraud or mislead." The result of such a rule would be in such cases as well as in cases without evil purpose to weaken the sanctions of the Act insofar as corporately organized business is concerned, since a fine is the only penalty to which a corporation can in the nature of things be subjected and is borne by the often innocent shareholders and not by the responsible management.

The exception which the court below recognized where an individual operates a corporation as his "alter ego" can do little to preserve the effectiveness of the Act. It introduces a vague test and will not be relevant in the great majority of violations.

It has been widely recognized that the purpose of criminal penalties cannot be achieved if their imposition is restricted to the corporation alone, and that the deterrent effect of criminal penalties becomes real only if visited also on the individuals responsible for corporate crimes. In consequence, case after case has upheld the imposition of criminal penalties on the responsible individuals, including the managers even though they may not have participated directly in the guilty act. These cases have ranged through all types of criminal statutes, including state food and drug acts and the federal Pure Food and Drugs Act of 1906. There is no reason for assuming that Congress in enacting this Act intended it to be less effective than the norm.

B. The decision below departs from the settled judicial and administrative construction of the 1906 act, which has heretofore been followed also under the present Act. The court's reason for this departure is inadequate. The only possibly relevant difference between the two acts, the court itself recognized was inconsequential. The ground actually relied on was available with at least equal force under the 1906 act and was never even seriously urged. The guaranty was never thought to be so restricted a protection. The broader protection has been recognized administratively since 1906.

The danger which the court below feared, from harassment of clerks who were unwitting tools, is

more apparent than real. As Judge Swan observed in dissenting, such a danger can be left to the good sense of the Administrator, the United States Attorneys, and the juries. Judge Swan's confidence is not misplaced, as is shown by this case, where the clerks have not been informed against, and by the constant administrative practice to that effect since 1906. The act, which is phrased generally, certainly should not be construed to relieve from liability clerks who act "with intent to defraud or mislead." But even if the implications of the guaranty provision relieved clerks from liability those implications would not relieve respondent, who alone had authority on behalf of the corporation to seek a guaranty.

ARGUMENT

A. The decision below finds no support in the language of the Act, and would cripple its effectiveness

There can be little question, as the court below recognized (R. 180), that literally applied the act penalizes the individuals responsible for an offense as well as the employer on whose behalf the offense was committed. The interdiction of the Act (Sec. 301, Appendix A, *infra*, p. 35) runs against "any person who" introduces or delivers "for introduction into interstate commerce * * * any food, drug, device, or cosmetic that is adulterated or misbranded." The word "person" is defined to mean, in addition to individuals

which it would clearly mean anyway, corporations and others. Thus the statute penalizes all individuals and corporations performing the prohibited acts.

The court below, however, held that the responsible human actors whose omissions or misdeeds cause the interdicted acts to occur are not within the reach of the penal provisions, but that only the dealer, in this case the corporation, to whom the acts or omissions of the agents are imputed, is penally answerable.² This interpretation was based on the guaranty provision of section 303 (e) (2); it is, as we shall demonstrate, not supported by that provision. Moreover, and even more clearly fatal, it would relieve from liability a corporate officer or employee even though he performed the interdicted acts on behalf of the corporation with intent to defraud or mislead.

The pattern of the Act is a composite. Section 201 (e) defines the word "person" to include any "individual, partnership, corporation, and association." Section 303 (a) imposes specified penalties, regardless of good faith or absence of intent to defraud or mislead, upon any "person" violating any of the prohibitions of section 301, and section 301 (a) prohibits the "introduction or delivery for introduction into interstate commerce of

² The only exception to this rule which the court recognized is where the individual is operating the corporation "as his 'alter ego' or agent," so that *he* is *its* principal (R. 181, 186, 187).

any food, drug, device, or cosmetic that is adulterated or misbranded." Section 303 (b), however, imposes more severe penalties upon violations of the same prohibitions when committed "with intent to defraud or mislead." Section 303 (e) (2) confers immunity on a "person" establishing a written guaranty of conformity from the person from whom he "received" the goods; this immunity is from prosecution under section 303 (a) and not from prosecution under section 303 (b).

The decision below was based on this guaranty provision; the reasoning was that the guaranty protected only the one who "received" the goods; the corporation, not its agents, received them; and Congress could not have intended the immunity conferred by the guaranty to be narrower than the scope of the penal provisions. There are several flaws in this reasoning. One is that suggested by Judge Swan in his dissent, that the fact that a conditional immunity is not as broad as a penal provision's coverage is no ground for narrowing the penal coverage. Congress may well have wanted it that way, and if one is satisfied that it did not the proper course is to construe the immunity to fit the unambiguous penal provisions rather than measuring the penal provisions to fit the ambiguous immunity. A second objection to the court's reasoning is that it misconstrued the effect of the guaranty authorized by Section 303 (e) (2). Clause (3) of section 303 (e) also au-

thorizes a guaranty, conferring immunity in the case of adulteration of coal-tar colors. This immunity differs from the former one in that (1) it is protective only if it provides that the colors come "from a batch certified in accordance with the applicable regulations promulgated by the Administrator," and (2) it must be signed by "the manufacturer," whereas the former guaranty may be signed by "the person * * * from whom he received in good faith the article." It is apparent that the word "received" in clause (2) was designed to enlarge the class that could give the guaranty, to include dealers as well as manufacturers, and not to restrict, as the court below thought, the class benefited by the guaranty.

The error of the restriction which the court below found in the immunity is further suggested by the anomaly which would result from holding that a clause (2) guaranty affords less protection than a clause (3) guaranty. The unauthorized introduction of new drugs (section 505, 21 U. S. C. Sec. 355) is a violation of section 301 (d) and the applicable immunity provision is therefore clause (2). Under the construction adopted below, since a manager could successfully claim immunity under a guaranty in the case of coal-tar colors, he could be convicted in the absence of a guaranty, but not so in the case of new drugs which might themselves be coal-tar products. This anomaly can be avoided, as we believe Congress intended, by construing the guaranty under

clause (2) to confer protection on both a dealer and its agents.

The position adopted by the majority below would go far to emasculate the statute. The court below recognized that the criminal penalties of section 303 (a) are, without regard to good faith or absence of intent to defraud or mislead, specifically made applicable to "any person" violating the prohibition of section 301 (a) (R. 180). While its reasoning, based on the guaranty provisions of section 303 (c), could not conceivably apply to a prosecution under section 303 (b) for acts done "with intent to defraud or mislead" since section 303 (c) does not purport to provide under any circumstances an immunity from the penalties of section 303 (b), it is nevertheless true that the prohibition of section 301 (a) is the same whether a prosecution for its violation is brought under section 303 (a) or section 303 (b). It is section 301 (a) that the court construes to apply only to the "dealer." But the same language cannot have two different meanings: it cannot apply to the drug dealer alone when the prosecution is brought under section 303 (a), and yet apply to other persons as well when the prosecution is brought under section 303 (b) for a violation resulting from a corporate agent's "intent to defraud or mislead." The word "person" in section 303 (a) obviously means, in the light of sec-

tion 201 (e), any individual, partnership, corporation, or association causing the act prohibited by section 301 (a),¹⁰ and section 303 (b) clearly applies only to the same persons, merely providing stricter penalties when such persons "act with intent to defraud or mislead." It follows, although the present case involves an unintentional violation, that the immunity conferred upon responsible corporate officers by the decision below logically would extend to such officers even when acting with intent to defraud or mislead.

The court below recognized individual liability only where the corporation acts as the "alter ego" of its manager. However, it would seem a safe assumption that Congress did not intend indi-

¹⁰ Even without aid from the definition of "person" contained in section 201 (e), there would be authority for construing the word "person" as used in section 303 (a) to include both a corporation and its responsible human agents. *City of Wyandotte v. Corrigan*, 35 Kan. 21 (1886); *Overland Cotton Mill Co. v. People*, 32 Colo. 263 (1904); *State v. Burnam*, 71 Wash. 199 (1912). The inclusion in the Act of section 201 (e) renders applicable the conclusion of Judge Hough in *United States v. MacAndrews & Forbes Co.*, 149 Fed. 823, 832 (C. C. S. D. N. Y.), writ of error dismissed, 212 U. S. 585, that "When the statute declares that certain acts notoriously to be accomplished under modern business conditions only through corporate instrumentality shall be misdemeanors, and further declares that the word 'person' as used therein shall be deemed to include corporations, such statute seems to me clearly passed in contemplation of the elementary principle that in respect of a misdemeanor all those who personally aid or abet in its commission are indictable as principals."

vidual liability to rest on the misty uncertainty involved in the disregard of corporate entity. A test based solely on whether the responsible individual is operating the corporation as his "alter ego" or agent is neither a desirable nor practicable test to be read into criminal law administration in the absence of clearer Congressional intent. The terms "alter ego," "agency," "instrumentality," "tool," "dummy," etc., would offer false certainty to a jury. "These concepts themselves need defining. At best they merely state results." Douglas and Shanks, *Insulation from Liability Through Subsidiary Corporations*, 39 Yale L. J. 193, 195 (1929). In a very real sense, a corporation is always the "agency" or "instrumentality" or "alter ego" for a particular purpose of those for whose benefit it is being operated; it exists only to do something on their behalf. The courts, however, have used these terms to describe the situation where dominion is "so complete, interference so obtrusive, that by the general rules of agency the parent will be a principal and the subsidiary an agent." *Berkey v. Third Avenue Ry. Co.*, 244 N. Y. 84, 95 (1926).¹¹ It would not be desirable nor practicable to make the responsibilities of ordinary corporate agents

¹¹ Corporations act only by human agents, and heretofore it has never been supposed that the responsibilities of agents for their acts begin only when the relation has been reversed and the ostensible principal has become the agent, and the ostensible agent the principal.

depend upon a test which, "enveloped in the mists of metaphor" (*Berkey v. Third Avenue Ry. Co.*, 244 N. Y. at 94), is so difficult of jury application. And, of course, confinement to that test would result in infrequent prosecution of the agent responsible for corporate wrongdoing. For rarely does the individual whose act or omission has resulted in a corporation's shipping adulterated or misbranded food or drugs in interstate commerce exercise such dominion and control over the corporation that it is in fact his "alter ego" or agent, and he its principal. In practical effect, therefore, the decision of the court below relieves responsible corporate officers of all the criminal penalties provided by sections 303 (a) and 303 (b) of the Federal Food, Drug, and Cosmetic Act, no matter how direct their causal relation to the corporate violation of section 301 (a).

In relieving the individuals most responsible for the wrongful conduct, the effect of the court's decision is to render much less effective, to the extent that the food and drug business is corporately organized, the penalties of fine and imprisonment provided by the Act. For a corporation as such cannot be imprisoned. Ordinarily, and particularly in large corporations, the persons penalized by seizures of the misbranded or adulterated articles¹² or by the assessment of

¹² While the seizure provisions of section 304 (21 U. S. C., Sec. 334) are unaffected by the instant decision, since they operate against the goods themselves and not against "per-

fines against the corporation are the shareholders, who may not even be aware of the penalty or have power to rectify the error; the monetary loss through seizure or fine often operates merely as a license fee to carry on the business in an illegal manner.¹³ The inequality that would thereby be created under the Act as between corporate business and business conducted by individual entrepreneurs or partners is apparent. A new advantage of incorporation would be provided.

Statutes imposing criminal liability for acts dangerous to the public even when committed

sons," recourse to seizure is inadequate to remove adulterated or misbranded goods from the market without enforcement by an impracticably large investigative staff. It is the combined effect of the criminal, injunction and seizure methods that gives the statute its efficacy in protecting the public.

¹³ In reporting S. 2800, one of the several bills introduced in the course of the legislative history of the Food, Drug, and Cosmetic Act of 1938, the Senate Committee on Commerce stated: "The penalties provided under the present Food and Drugs Act have proved wholly inadequate to bring about substantial compliance with the law on the part of those manufacturers who regard an occasional small fine as an inexpensive license to carry on their illicit operations." Sen. Rep. No. 493, 73d Cong., 2d Sess., S. 2800, p. 20 (Charles Wesley Dunn, *The Federal Food, Drug, and Cosmetic Act: A Statement of its Legislative Record* (New York, 1938), pp. 128-129); see also Sen. Rep. No. 361, 74th Cong., 1st Sess., S. 5, p. 27 (Dunn, 261). The old Act (21 U. S. C. [1934 Ed.], Secs. 1-26) provided no imprisonment for a first offense (*Frank v. United States*, 192 Fed. 864, 868 (C. C. A. 6)), and a maximum of one year's imprisonment and \$300 fine for subsequent offenses (Sec. 2). A 1934 amendment treated more severely improper labelling of seafood (Sec. 14a).

without intent to harm, have as their aim the inculcation of an attitude of vigilant care on the part of those responsible for the operation of the industries affected.¹⁴ *United States v. Balint*, 258 U. S. 250, 252. Enforcement of the present statute has therefore frequently proceeded directly against managerial personnel (see p. 32, *infra*), on the view that the prospect of a jail sentence in a

¹⁴ The need for such an attitude as well as the effect of the rule for which we contend in inducing it are both illustrated by the instant record. Not all pure digitalis leaf is of the same potency (R. 72), one consequence of which is that its potency cannot be determined by chemical analysis but only by its effect on animals (R. 72). Arner and Co., which manufactured the digitalis tablets for the defendant corporation, added sugar and starch to the digitalis to make tablets, air-dried them to avoid loss of potency, and eventually sent them to the defendants (R. 132, 138-139, 129). Arner did not test them for potency at any time prior to the time when they were found deficient by the Government (R. 135, 136). There was no evidence that their potency was tested by defendant corporation before it sold them, and as such evidence would have been a complete defense on two counts for both defendants we may assume that such a test was not made. Respondent was general manager of the corporation (R. 143), and had devised its operating system (R. 129). It was he, therefore, who had the authority and opportunity to provide for such a test and he who failed to do it, and he alone can pass such a test into the operational routine as a protection against like future delinquencies.

The court's charge made respondent's authoritative position crucial. The charge instructed the jury that it could convict "if the evidence establishes to your satisfaction that it [the shipment] was made under authority conferred by him as general manager upon his subordinates, including the receiving and shipping clerk" (R. 164). An employee in a nonauthoritative position was not within the scope of this charge.

criminal case is the most effective deterrent to violations. By increasing the severity of the penalties where the acts are done with intent to defraud or mislead, the statute seeks also to relate the extent of the punishment to blameworthiness. The decision below nullifies this aim in large measure.

More than thirty years ago Woodrow Wilson stated:¹⁵

Corporations do not do wrong. Individuals do wrong, the individuals who direct and use them for selfish and illegitimate purposes, to the injury of society and the serious curtailment of private rights. Guilt, as has been very truly said, is always personal. You cannot punish corporations. Fines fall upon the wrong persons, more heavily upon the innocent than upon the guilty, as much upon those who knew nothing whatever of the transactions for which the fine is imposed as upon those who originated and carried them through—upon the stockholders and the customers rather than upon the men who direct the policy of the business. * * * *

Society cannot afford to have individuals wield the power of thousands without personal responsibility. * * *

¹⁵ Woodrow Wilson, *The Lawyer and the Community*, 35 Am. Bar Ass'n Repts. 419, 427, 429, 431-432 (1910).

In respect to the responsibility which the law imposes in order to protect society * * * against wrongs which are not breaches of contract but offenses against the public interest, the common welfare, it is imperative that we should regard corporations as merely groups of individuals, from which it may, perhaps, be harder to pick out particular persons for punishment than it is to pick them out of the general body of unassociated men, but from which it is, nevertheless, possible, to pick them out—possible not only, but absolutely necessary if business is ever again to be moralized, * * *

These observations are appropriate here, where neither the deterrent purpose of punishment, nor a purpose to do justice by relating punishment to responsibility and blameworthiness, is adequately served by punishing the corporation alone (and indirectly shareholders who may be innocent and powerless to rectify the error or even unaware of the penalty) and relieving entirely the very persons whose acts or omissions have had to be imputed to the corporation in order to justify its conviction. It would be an anomaly, fraught with serious consequences,¹⁶ for the im-

¹⁶ With respect to civil liability in tort the court in *Nunnelly v. Southern Iron Co.*, 94 Tenn. 397, 416 (1895), pointed out: "To permit an agent of a corporation, in carrying on its business, to inflict wrong and injuries upon others, and then shield himself from liability behind his vicarious character, would often both sanction and encourage the perpetration of fla-

putation of a criminal act to a corporate principal to leave the act itself bare of its criminal character so far as the responsible human actor is concerned. That anomaly has heretofore been avoided. The principle has been enforced that a corporate agent, through whose act, default, or omission the corporation commits a crime, is himself guilty individually of that crime. This principle has been applied whether the crime be one requiring wrongful intent, or one not requiring such intent.¹⁷ Moreover, it has been applied not only to those corporate agents who themselves commit the criminal act, but also to those who by virtue of their managerial positions or other similar relation to the actor can be deemed responsible for its commission. This principle has received application in a wide variety of situations, some of which are the following:

1. Engaging on behalf of corporation in business conditioned on payment of license fees, without payment of such fees.—(*City of Wyandotte*

grant and wanton injuries by agents of insolvent and irresponsible corporations.” Citing this case, the court in *State v. Gilbert*, 213 Wis. 196, 217-218, (1933), held that the same principle is applicable to impose criminal liability upon “directors, officers, and agents of a corporation when funds intrusted to it have been converted, even though they were used for the benefit of the corporation and not the officers concerned.” See also *People v. Duke*, 19 Misc. (N. Y.) 292, 295-296 (1897).

17 Where the crime is one a corporation is not deemed capable of committing, the individuals alone are liable. See *State v. Ross*, 55 Ore. 450, 466 (1909).

v. Corrigan, 35 Kan. 21, 26 (1886); *Crall v. Commonwealth*, 103 Va. 855, 859 (1905).)

2. Maintenance of nuisance.—(*People v. Detroit White Lead Works*, 82 Mich. 471 (1890).)

3. Violation of child labor laws.—(*Overland Cotton Mill Co. v. People*,¹⁸ 32 Colo. 263 (1904).)

4. Embezzlement, larceny, or obtaining money by issuance of worthless checks, on behalf of corporations.—(*State v. Ross*, 55 Ore. 450 (1909); *State v. Thomas*, 123 Wash. 299 (1923); *Milbrath v. State*, 138 Wis. 354 (1909); *State v. Gilbert*, 213 Wis. 196 (1933); *People (Belleci) v. Klinger*, 164 Misc. (N. Y.) 530, 533 (City Magistrate's Court, Borough of Manhattan, 1937); *State v. Cooley*,¹⁹ 141 Tenn. 33 (1918);)

¹⁸ The conviction was sustained despite the fact that the officers of the corporation had issued specific instructions for bidding the employment of children under fourteen. For decisions that the criminal liability of a corporate or individual principal may be based upon an agent's act in violation of his express orders, "if within the general scope of the agent's authority," see, also, *People v. Schwartz*, 28 Cal. App. (2d) 775, 781 (1937); *Scott v. State*, 171 Wis. 487 (1920).

¹⁹ In this case a corporate official in his capacity as such signed a check with the corporation as drawer. He was held liable criminally under a statute applicable to him only if he was the "maker or drawer," a position he did not occupy under section 20 of the Uniform Negotiable Instruments Law (Williams Tenn. Code Ann., 1934, Sec. 7344). The court concluded that the purpose of the statute could be effectuated only if it applied to the individual acting on behalf of the corporation. *Contra, People v. Fleishman*, 133 Misc. (N. Y.) 288 (1928) (criticized in 29 Col. L. Rev. 357, and 42 Harv. L. Rev. 824); and *State v. Parker*, 112 Conn. 39 (1930) (criticized in 40 Yale L. J. 307); the *Fleishman* and *Parker* cases are also questioned in Stevens, *Corporations* (1936), p. 325.

5. Violations of Sherman Anti-Trust Act.—
(United States v. MacAndrews & Forbes Co., 149 Fed. 823, 832 (C. C. S. D. N. Y.), writ of error dismissed, 212 U. S. 585; *Patterson v. United States*, 222 Fed. 599 (C. C. A. 6), certiorari denied, 238 U. S. 635; *United States v. Winslow*, 195 Fed. 578, 581 (D. Mass.); *United States ex rel. McGrath v. Mathues*, 6 F. (2d) 149 (E. D. Pa.); *United States v. General Motors Corp.*, 26 F. Supp. 353 (N. D. Ind.), affirmed, 121 F. (2d) 376 (C. C. A. 7), certiorari denied, 314 U. S. 618; *United States v. Atlantic Commission Co., Inc.*, 45 F. Supp. 187, 194 (E. D. N. C.)).²⁰

6. Violations of state pure food laws.—(*State v. Burnam*, 71 Wash. 199 (1912); *People v. Schwartz*, 28 Cal. App. (2d) 775 (1937); *Turner v. State*, 171 Tenn. 36 (1937); *State v. Brown*, 151 Minn. 340, 343 (1922).)

It is significant that liability of managerial officers has not rested on their having knowledge of or a physical part in the guilty act. Where the crime does not require wrongful intent, an omission or failure to act becomes an entirely sufficient basis of a responsible corporate agent's liability. In such cases it is sufficient that it was within the

²⁰ The decisions usually so held independently of section 14 of the Clayton Act (38 Stat. 736; 15 U. S. C., Sec. 24); as Judge Wyche pointed out in *United States v. Atlantic Commission Co.*, *supra*, if the officers or agents are "personally charged with participation in the conspiracy there is no necessity for the application of Section 14 of the Clayton Act". (45 F. Supp. at 194).

agent's power by virtue of the relationship he bore to the company to have prevented the act complained of. See, for example, *Overland Cotton Mill Co. v. People*, *supra*; *State v. Burnam*, *supra*; and *People v. Schwartz*, *supra*. It would be difficult to conceive of a more responsible corporate officer, or one falling within more clearly applicable principles of the criminal liability of corporate officers, than respondent Dotterweich in the present case.²¹

B. The decision of the court below overturns a long-established administrative and judicial construction of similar provisions of the predecessor act of 1906 and of similar state statutes, on no adequate basis contained in the 1938 Act

Section 12 of the Pure Food and Drugs Act of 1906 (Act of June 30, 1906, c. 3915, 34 Stat. 768, 772), which the Act of 1938 supplanted, provided that—

the act, omission, or failure of any officer, agent, or other person acting for or employed by any corporation, company, society, or association, within the scope of his employment or office, shall in every case be also deemed to be the act, omission, or fail-

²¹ As previously shown, the court's reversal of respondent's conviction does not rest upon the basis that he had not personally made or ordered the shipments constituting violations of the Act, or upon a view that he was not responsible therefor, but upon a basis that would relieve him of liability even had he personally made or ordered the shipments and done so with intent to defraud or mislead.

ure of such corporation, company, society, or association as well as that of the person. Subsequently the aiding and abetting statute (Section 332 of the Criminal Code [Mar. 4, 1909, c. 321, 35 Stat. 1152; 18 U. S. C., Sec. 550]) was enacted, which provides:

Whoever directly commits any act constituting an offense defined in any law of the United States, or aids, abets, counsels, commands, induces, or procures its commission, is a principal.

Under the latter statute alone, without aid from the one defining the crime, corporate officers may be indicated as aiders and abettors of their corporate principal (*Kaufman v. United States*, 212 Fed. 613 (C. C. A. 2); *Wood v. United States*, 204 Fed. 55 (C. C. A. 4), certiorari denied *sub nom. Rhea v. United States*, 229 U. S. 617). So far as misdemeanors are concerned, however, Section 332 of the Criminal Code seems merely to have adopted the previously existing rule that—“When congress creates a statutory misdemeanor we must assume that it is done * * * with the intent that aiders and abettors, as well as the actual doers of the crime, may be punished under it.” * * * *United States v. Snyder*, 14 Fed. 554, 556 (D. Minn.). It follows that neither Section 12 of the Act of 1906 nor Section 332 of the Criminal Code was ever really essential to the prosecution of responsible corporate officers under

the Act of 1906; and without reliance upon either the courts rejected, in the early years of the Act's operation, the suggestion that criminal liability thereunder was restricted to nominal principals. *United States v. Mayfield*, 177 Fed. 765 (N. D. Ala.); *United States v. Buffalo Cold Storage Co.* 179 Fed. 865 (W. D. N. Y.); *United States v. Kellett* (D. Utah), reported in White and Gates, *Decisions of Courts in Cases under the Federal Food and Drugs Act* (1934), pp. 711, 713.

This was the long-standing construction of the 1906 Act. The court below in the present case recognized that the omission from the 1938 Act of the language of Section 12 of the 1906 Act was without significance, stating that such language "was doubtless omitted as unnecessary because it states an obvious general principle of agency." (R. 281).²² The court's decision therefore is

²² The legislative history of the 1938 Act is silent as to the reason for the omission. The first bill introduced (S. 1944, 73d Cong., 1st Sess.) contained the following provision: "Sec. 18. (a) When construing and enforcing the provisions of this Act, the act, omission, or failure of any officer, employee, or agent acting for or employed by any person, within the scope of his employment or office, shall in every case be deemed to be the act, omission, or failure of such person, as well as that of the officer, employee, or agent. (b) Whenever a corporation or association violates any of the provisions of this Act, such violation shall also be deemed to be a violation of the individual directors, officers, or agents of such corporation or association who authorized, ordered, or did any of the acts constituting, in whole or in part, such violation." See Dunn, *The Federal Food, Drug, and Cos-*

not based on some feature in the 1938 Act different from the 1906 Act. In fact, the legislative history of the 1938 Act shows clearly that a major purpose of the new Act was to increase the severity

metie Act: A Statement of Its Legislative Record (New York, 1938), p. 47. This same language was carried forward through several successive bills: S. 2000, 73d Cong., 2d Sess., Sec. 18 (Dunn, 63); S. 2800, 73d Cong., 2d Sess., Sec. 18 (Dunn, 83, 105); S. 5, 74th Cong., 1st Sess., Sec. 709 (Dunn, 205, 231). In S. 5, 74th Cong., 2d Sess., Sec. 707, as reported to the House of Representatives by the Committee on Interstate and Foreign Commerce, the language of subsection (b), as quoted above was changed to read: "Whenever a corporation or association violates any of the provisions of this Act, unless otherwise provided, such violation shall also be deemed to be a violation by the individual directors, officers, or agents of such corporation or association who personally ordered, or did any of the acts constituting, in whole or in part, such violation" (Dunn, 545). The Senate agreed to this provision (Dunn, 599, 613, 619). The bill containing it died in the House, however (Dunn, 633). S. 5, 75th Cong., 1st Sess., Sec. 2 (f), as introduced into the Senate, provided: "The term 'person' includes individual, partnership, corporation, and association. Unless otherwise hereinafter provided, the act, omission, or failure of any director, officer, employee, or agent acting for or employed by any person, within the scope of his employment, agency, or office, shall in every case be deemed to be the act, omission, or failure of such person, as well as that of the director, officer, employee, or agent who personally ordered or did any of the acts constituting, in whole or in part, such violation". (Dunn, 638). As the bill was reported by the Senate Committee on Commerce, however, the words "who personally ordered or did any of the acts constituting, in whole or in part, such violation," had been stricken (Dunn, 657). In Committee Print No. 3, August 1937, as recommended by the subcommittee of the Committee on Interstate and Foreign Commerce of the House, there appears for the first time the provision of

and effectiveness of the penal provisions especially by way of jail sentences,²³ rather than to render them less effective as the decision below unquestionably would do.

The oblique application made by the court of Section 303 (c) of the 1938 Act could as readily have been made of Section 9 of the 1906 Act (34 Stat. 768, 771), which similarly exempted a person from prosecution "when he can establish a guaranty signed by the wholesaler, jobber, manufacturer, or other party residing in the United States *from whom he purchases* such articles * * *." [Italics supplied.] Technically the corporate agent or employee is even less the one who "purchases" the articles within the language of the

section 201 (e) as finally enacted, to the effect merely that "The term 'person' includes individual, partnership, corporation, and association" (Dunn, 753).

The only conclusion to be derived from the legislative history is that Congress failed to enact a provision that would have required a corporate officer to have "personally" ordered or done an act constituting a violation, in order to be held personally responsible therefor, and that it felt that it was unnecessary to include language of the 1906 Act that merely "states an obvious general principle of agency."

²³ Sen. Rep. No. 493, 73d Cong., 2d Sess., S. 2800, p. 20 (Dunn, 128-129); Sen. Rep. No. 361, 74th Cong., 1st Sess., S. 5, p. 27 (Dunn, 261); Sen. Rep. No. 646, 74th Cong., 1st Sess., S. 5, p. 12 (Dunn, 487-488); Sen. Rep. No. 91, 75th Cong., 1st Sess., S. 5, p. 6 (Dunn, 681); Sen. Rep. No. 152, 75th Cong., 1st Sess., S. 5, p. 6 (Dunn, 692); H. Rep. No. 2755, 74th Cong., 2d Sess., S. 5, p. 4 (Dunn, 553); H. Rep. No. 2139, 75th Cong., 3d Sess., S. 5, p. 3 (Dunn, 816); 75 Cong. Rec. 4572, 8960 (Dunn, 90, 164); 83 Cong. Rec. 7775 (Dunn, 849).

1906 Act than he is the one who "received" them within the language of the 1938 Act. Yet the argument which is the whole basis of the court's decision never found acceptance under the 1906 Act. For example, in *United States v. Mayfield*, 177 Fed. 765 (N. D. Ala.), the court made it clear that only because the corporation could not establish a guaranty were its officers criminally liable under the 1906 Act. In fact, so far as we have been able to ascertain, the argument was never even seriously pressed. It has never found acceptance under any of the thirty-one state statutes, cited in Appendix B, containing substantially the same coverage and guaranty provisions as those of the 1906 and 1938 federal statutes. As previously shown the criminal penalty provisions of these state statutes have been applied to responsible agents occupying positions comparable to respondent's here, and have never been restricted to the "dealer" alone (*State v. Burnam*, 71 Wash. 199 (1912); *People v. Schwartz*, 28 Cal. App. (2d) 775 (1937); *Turner v. State*, 171 Tenn. 36 (1937); and the state courts have regarded the guaranty as protecting the employees. *People v. Schwartz*, *supra*; *Turner v. State*, *supra*; *Commonwealth v. Lutz*, 137 Pa. Super. 449 (1939). What the court below has done, therefore, is to reject under the 1938 Act a long-standing construction of the 1906 Act and of similar state statutes, on a ground that provides no basis

for distinguishing the 1938 Act. It would be strange if Congress had intended such a change, with the legislative history silent on the point except by way of showing a purpose to provide in the 1938 Act more severe and effective criminal penalties.

The policy of the Food and Drug Administration, in the exercise of its administrative discretion, has been to avoid prosecution of underlings acting under instructions.²⁴ In the calendar year ended December 31, 1942, more than 400 criminal cases were brought under the 1938 Act. About half (208) involved corporate defendants, and in approximately 30 percent of these (61) one or more officers or employees were joined with the corporation as defendants. Prosecutions of individuals have never been restricted to those who dominate the enterprise but have included persons with varying but substantial degrees of responsibility. The individual defendants have been persons such as respondent Dotterweich—persons with policy-making and discretionary functions quite apart from whether or not they control the whole enterprise—since they are the ones who have the power to initiate precautionary measures, to avoid violations of the Act, and since jail sentences against such persons constitute a far

²⁴ The present case serves as an illustration. The workmen who performed the actual operations of bottling, labeling, and shipping were not made defendants. There is no suggestion of a guaranty here.

more effective deterrent than either a fine assessed against the corporation or seizure of the offending goods. The existing administrative practice, contemplating enforcement against responsible agents, officers, and employees who are above the level of mere hired hands following instructions, is a continuation of over thirty years' enforcement policy under the predecessor Act of 1906. Moreover, under both the 1906 and 1938 Acts the administrative practice has been to regard the guaranty as running with the goods so as to protect the employees as well as the dealer. This practice has been thought to be required by the Act rather than being the product of administrative discretion.

If the guaranty provision does limit the scope of the penal provisions, contrary to our view, it would seem that the proper interpretation of the limitation would be to exclude criminal liability of mere clerks and underlings, who would be without authority to obtain a guaranty on behalf of the corporation, and to impose criminal liability on the responsible officers who had authority on behalf of the corporation to obtain a guaranty and who failed to do it. Such a view would support the conviction of respondent, who clearly was the corporate official with authority to procure a guaranty. We believe, however, that the statute should not be construed to relieve clerks of liability in proper cases, since it is inconceivable

that Congress intended to spare clerks who act with "intent to defraud or mislead" or who negligently and contrary to instructions act so as to cause a violation of the Act. As we have seen, the statute speaks in general terms and contains no distinction between well-intentioned and other clerks. The distinction must be drawn administratively.

CONCLUSION

For the foregoing reasons, the judgment of the court below should be reversed and that of the district court affirmed.

Respectfully submitted.

✓ CHARLES FAHY,

Solicitor General.

✓ WENDELL BERGE,

Assistant Attorney General.

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Attorney.

AUGUST 1943.

APPENDIX A

The Federal Food, Drug, and Cosmetic Act of 1938, 52 Stat. 1040, 21 U. S. C., Sec. 301 *et seq.*, in pertinent part provides:

SEC. 201 (21 U. S. C., Sec. 321). For the purposes of this Act—

* * * * *

(e) The term "person" includes individual, partnership, corporation, and association.

* * * * *

SEC. 301 (21 U. S. C., Sec. 331). The following acts and the causing thereof are hereby prohibited:

(a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded.

* * * * *

(h) The giving of a guaranty or undertaking referred to in section 303 (e) (2), which guaranty or undertaking is false, except by a person who relied upon a guaranty or undertaking to the same effect signed by, and containing the name and address of, the person residing in the United States from whom he received in good faith the food, drug, device, or cosmetic; or the giving of a guaranty or undertaking referred to in section 303 (e) (3), which guaranty or undertaking is false.

* * * * *

SEC. 303 (21 U. S. C., Sec. 333). (a) Any person who violates any of the provisions of section 301 shall be guilty of a misdemeanor and shall on conviction thereof be subject to imprisonment for not more than one year, or a fine of not more than \$1,000, or both such imprisonment and fine; but if the violation is committed after a conviction of such person under this section has become final such

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person shall be subject to imprisonment for not more than three years, or a fine of not more than \$10,000, or both such imprisonment and fine.

(b) Notwithstanding the provisions of subsection (a) of this section, in case of a violation of any of the provisions of section 301, with intent to defraud or mislead, the penalty shall be imprisonment for not more than three years, or a fine of not more than \$10,000, or both such imprisonment and fine.

(c) No person shall be subject to the penalties of subsection (a) of this section, * * * (2) for having violated section 301-(a) or (d), if he establishes a guaranty or undertaking signed by, and containing the name and address of, the person residing in the United States from whom he received in good faith the article, to the effect, in case of an alleged violation of section 301 (a), that such article is not adulterated or misbranded, within the meaning of this Act, designating this Act, or to the effect, in case of an alleged violation of section 301 (d), that such article is not an article which may not, under the provisions of section 404 or 505, be introduced into interstate commerce; or (3) for having violated section 301 (a), where the violation exists because the article is adulterated by reason of containing a coal-tar color not from a batch certified in accordance with regulations promulgated by the Administrator under this Act, if such person establishes a guaranty or undertaking signed by, and containing the name and address of, the manufacturer of the coal-tar color, to the effect that such color was from a batch certified in accordance with the applicable regulations promulgated by the Administrator under this Act.

APPENDIX B

The Food and Drug Laws of the following States contain coverage and guaranty provisions which are substantially the same as those of the Federal Pure Food and Drugs Act of 1906 and the Federal Food, Drug, and Cosmetic Act of 1938:

1. Alabama—Code of Alabama, 1940, Title 2, Sections 1 and 331.
2. Arizona—Code Annotated, 1939, See, 68-410, See, 68-412.
3. Arkansas—Part 1 of Ch. 70 of Pope's Digest, as amended by Act 10,190, Reg. Sess. of 1939, See, 6008, See, 6015.
4. California—Ch. 3 of Div. XXI of Health and Safety Code, added by Ch. 731, Laws of 1939; amended by Ch. 1042, 1147, 1149, Laws of 1941, See, 26514, See, 26520.
5. Colorado—Statutes Annotated, 1935, Ch. 69, Sections 3, 9, 11.
6. Connecticut—See, 886e-919e of Ch. 135b of 1939 Supp. to General Statutes, Ch. 364, Laws of 1939 as amended by House Bill 2693, effective 1941, See, 3- (e), See, 6- (e).
7. Florida—Ch. 19656 (No. 661), Laws of 1939, See, 2- (b), See, 5- (b).
8. Georgia—Code Annotated, See, 42-108, See, 42-115, See, 42-9901.
9. Idaho—Code Annotated, 1932, See, 36-302, See, 36-311, See, 36-313.
10. Indiana—Burns Indiana Statutes Annotated, See, 35-1230 (e), See, 35-1233 (e).
11. Kansas—General Statutes Annotated, See, 65-602, See, 65-609, See, 65-610.
12. Kentucky—Revised Statutes, 1942, See, 217.060, See, 217.160, See, 217.990.

13. Louisiana—Act No. 142, Acts of 1936, Amended by Act No. 185, Acts of 1942, See, 2 (e), See, 20 (d).
14. Maryland—Flack's Annotated Code, 1939, Art. 43, See, 189 and See, 193.
15. Massachusetts—Annotated Laws, Ch. 94, See, 191 and See, 193.
16. Michigan—Statutes Annotated, Title 14, See, 14-787 and See, 14-781.
17. Missouri—Statutes Annotated, Art. 2, See, 13027, See, 13028, See, 13029.
18. Montana—Revised Code, 1935, Ch. 237, See, 2578 and See, 2588.
19. Nebraska—Compiled Statutes, 1929, See, 81-908, See, 81-910, See, 81-911.
20. New Jersey—Statutes Annotated, Sec. 24:5-2, See, 24:4-3, See, 24:17-1.
21. New York—McKinley's Consolidated Laws, Art. 17, Bk. 2B, See, 198.2, See, 214.
22. North Carolina—S. Bill No. 232, Reg. Sess., 1939, See, 2 (b), See, 5 (b).
23. Oklahoma—Oklahoma Statutes, 1941, Title 63, See, 182 and See, 260.
24. Pennsylvania—Compiled Statutes (Purdon's), 1936, Title 31, See, 2 and See, 5.
25. Rhode Island—General Laws 1938, Ch. 269, Ch. 1 and Ch. 7.
26. South Carolina—Code, 1942, See, 5128-27 (1) and (5).
27. South Dakota—Code, 1939, See, 22.0404, See, 22.0407, See, 22.9905.
28. Tennessee—Ch. 120, S. 568, 1941, See, 2 (b) and See, 5 (b).
29. Virginia—S. Bill 310, Reg. Sess. 1940, See, 2 (b) and See, 5 (b).
30. Washington—Pierce's Code, 1929, See, 2535 and See, 2539.
31. Wyoming—Revised Statutes, 1931, Supp. 1940, See, 45-117, See, 45-118.

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No. 5

Supreme Court of the United States

October Term, 1943

THE UNITED STATES OF AMERICA, PETITIONER

vs.

JOSEPH H. DREYER, JR.,

RE WITNESS CERTIFICATE TO THE UNITED STATES CIRCUIT
COURT OF APPEALS FOR THE SECOND CIRCUIT

RE BRIEF FOR THE UNITED STATES IN REPLY

In the Supreme Court of the United States

OCTOBER TERM, 1943

No. 5

THE UNITED STATES OF AMERICA, PETITIONER
v.

JOSEPH H. DOTTERWEICH

ON WRIT OF CERTIORARI TO THE UNITED STATES CIRCUIT
COURT OF APPEALS FOR THE SECOND CIRCUIT

MEMORANDUM FOR THE UNITED STATES IN REPLY

Respondent has not seriously endeavored in his brief to support the decision below on the ground relied on by the court. Instead he urges grounds which, we submit, the court below properly decided against him for the reasons hereinafter set forth.¹

I. ADMINISTRATIVE NOTICE AND HEARING AS PROVIDED BY SECTION 305 ARE NOT A JURISDICTIONAL PREREQUISITE TO PROSECUTION UNDER THE ACT

In Point I of respondent's brief (pp. 10-15) he contends that under Section 305 (21 U. S. C.

¹ Point Two of respondent's brief (pp. 15-21) is evidently intended to support the decision below on the ground relied on by the court. It contains, we believe, nothing not answered in the opening brief of the United States.

335) a notice addressed to him personally was a condition precedent to his lawful prosecution, and that the court below erred in holding (R. 179) that the provision of Section 305 for administrative notice and hearing "was an administrative direction to the Administrator rather than a jurisdictional requirement for criminal proceedings." The statutory notice was in fact given to the corporate defendant and answered by respondent as its general manager. (See R. 114-115, 167, 178-179). However, we need not consider the sufficiency as to respondent of a notice addressed to the corporation, since it is clear that as to any defendant the provision for administrative notice and hearing is no more than a direction to the Administrator.

This was the holding of *United States v. Morgan*, 222 U. S. 274, under the comparable provision of Section 4 of the Pure Food and Drugs Act of 1906 (c. 3915, 34 Stat. 768, 769). Under Section 5 of that Act a United States attorney was required to institute criminal proceedings upon a report by the Secretary of Agriculture of a violation, and also upon the presentation to the district attorney, by state health officials, of satisfactory evidence of a violation. But there was no requirement of administrative notice and hearing by state health officials before reporting a violation to the district attorney; and this Court therefore concluded that "the very fact that he

must" institute proceedings on their presentation to him of satisfactory evidence of a violation "recognizes that he may begin proceedings against a defendant who has not been given a notice and an opportunity to be heard," and that "the fact that the statute compels him to act in one case, does not deprive him of the power voluntarily to proceed in that and every other case under his general powers" (222 U. S., at 280, 281).²

Contrary to respondent's contention (Br. 11) that the phraseology of Section 305 of the 1938 Act indicates an intention to avoid the result of the *Morgan* decision, the 1938 Act strengthens the basis for the application of that decision by omitting any provision making it mandatory in any case for a district attorney to institute criminal proceedings upon the recommendation of the Federal Security Administrator. See *Helco Products Co., Inc. v. McNutt* (App. D. C.), decided June 28, 1943. And the legislative history of the 1938 Act clearly sustains the conclusion of the court below in this case, and of the court in *United States v. Commercial Creamery Co.*, 43 F.

² This Court also emphasized (222 U. S., at 281-282) that "there is certainly no presumption that a law passed in the interest of the public health was to hamper district attorneys, curtail the powers of grand juries or make them, with evidence in hand, halt in their investigation and await the action of the Department [of Agriculture]. To graft such an exception upon the criminal law would require a clear and unambiguous expression of the legislative will."

Supp. 714, 715 (E. D. Wash.), that no change from this Court's construction of Section 4 of the 1906 Act was effected. One of the several bills introduced (S. 5, 75th Cong., 1st sess.), had it been enacted in its original form, would have given support to respondent's position, by providing expressly as follows:

SEC. 7. Before reporting any violation of this Act to any United States attorney for institution of criminal proceedings, the Secretary shall, in accordance with regulations prescribed by him, afford appropriate notice and opportunity for hearing to the person against whom the proceedings are contemplated. * * *

SEC. 9. It shall be the duty of each United States attorney to whom the Secretary, *consistently with the provisions of sections 6 and 7*, reports any violation for institution of criminal, libel of information for condemnation, or other proceedings under this Act, or to whom any health, food, or drug officer of any State or Territory, or political subdivision thereof, presents evidence satisfactory to the United States attorney of any such violation *and that appropriate notice and opportunity for hearing has been afforded to the person against whom the proceedings are contemplated*, to cause appropriate proceedings to be instituted in the proper courts

of the United States without delay. * * *
 [Italics supplied.]

As the bill was reported out of committee to the Senate on February 15, 1937, the specific requirement of a finding by the United States attorney that notice and hearing have been afforded was limited to criminal proceedings;⁴ and in this form the bill passed the Senate on March 9, 1937.⁵ It was referred to the House Committee on Interstate and Foreign Commerce, of which Representative Lea, of California, was chairman.⁶ A subcommittee of that committee prepared and recommended a draft known as Committee Print No. 3, of August 19, 1937,⁷ and S. 5 was reported by the committee to the House in this form on April 14, 1938.⁸ Section 305 thereof was the same as Section 305 of the law as finally enacted, except for the later insertion of the words "by the Secretary;" and the provision of Section 9 of S. 5, as it had passed the Senate, was wholly eliminated. On the floor of the House, Representatives Lowey and Clason objected to Section 305 on the ground

⁴ See Dunn, *Federal Food, Drug, and Cosmetic Act: A Statement of Its Legislative Record* (New York, 1938), p. 643.

⁵ See Dunn, *op. cit., supra*, note 3, p. 663.

⁶ 81 Cong. Rec. 2019 (1937).

⁷ 81 Cong. Rec. 2096 (1937).

⁸ See Dunn, *op. cit., supra*, note 3, p. 752.

⁹ 83 Cong. Rec. 5465 (1938); H. Rep. 2139, 75th Cong., 3d sess.

that it would, in their opinion, confer upon an administrative agency the power to determine whether criminal proceedings should or should not be instituted and would bring about delays in prosecution.⁹ In reply Mr. Lea, who was chairman of the subcommittee that had prepared, and of the committee which had reported, the House bill, stated that under Section 305 "it is not necessary for the prosecuting attorney to await a report by the Department of Agriculture;" that Section 305 "simply refers to the administrative duty of the Secretary;" and that "The law speaks for itself, and there are no strings on the Department of Justice or on the grand jury. They can proceed whenever they like."¹⁰ As a result there was no further discussion of Section 305. The bill with Section 305 unchanged passed the House,¹¹ the House and Senate conferees adopted the House bill;¹² and the Senate agreed to the conference report without debate.¹³

We therefore submit that the decision of this Court in the *Morgan* case and the legislative history of the 1938 Act provide a conclusive answer to respondent's contention on this point.

⁹ 83 Cong. Rec. 7791-7794 (1938).

¹⁰ 83 Cong. Rec. 7794 (1938). See, also, H. Rep. No. 2139, 75th Cong., 3d sess., p. 5 (Dunn, pp. 818-819): "Section 305 * * * merely requires continuation of a practice that has been followed in the enforcement of the present law."

¹¹ 83 Cong. Rec. 7903 (1938).

¹² H. Rept. No. 2716, 75th Cong., 3d sess.

¹³ See 83 Cong. Rec. 8731-8738 (1938).

II. THE VERDICT IS SUPPORTED BY THE EVIDENCE

Respondent's contention that the verdict is not supported by the evidence (Br. 21-25) was considered by the court below and unanimously rejected (R. 178). Apparently in this Court respondent renews this contention only as to the second and third counts, which charged adulteration and misbranding of the digitalis tablets.

The Government, in its opening brief, p. 5, footnote 6, has set forth, with the record references, the history of the digitalis tablets in question. Respondent asserts, nonetheless, that the evidence does not establish that the deterioration of the tablets did not occur after Dr. Tagett, to whom Buffalo Pharmacal Co. had sold them, had received and opened them. The record is, however, not helpful to respondent. Dr. Tagett, called by the Government, testified that he kept the bottle in his drug room, adjoining his office, which he kept at a uniform, moderate temperature (R. 60). The bottle was kept tightly stoppered at all times except when the stopper had to be removed for tablets to be taken from the bottle (R. 60, 64). Dr. Tagett testified on cross-examination that in his experience digitalis tablets did not lose potency when kept as he kept them (R. 64-65).¹⁴ The Food and Drug inspector who

¹⁴ Respondent's counsel also elicited from Dr. Tagett on cross-examination the fact that a subsequent batch of digitalis which Dr. Tagett purchased from Buffalo Pharmacal Co. caused his patients nausea and vomiting (R. 63, 67).

obtained the bottle from Dr. Tagett testified that when he collected the bottle it was in the doctor's drug room, and was capped (R. 22). Dr. Chapman, an expert witness whom respondent's counsel had previously built up as one of the outstanding experts on digitalis (R. 82-83), testified that deterioration of the tablets under the conditions in which Dr. Tagett had kept them was "unlikely" (R. 107-108).¹⁵ Moreover, he testified that any deterioration of digitalis tablets is most likely to occur in "the first few weeks" after preparation (R. 108). He also testified that if the tablets in question "had been prepared months before," they would not be likely to deteriorate under the conditions in which Dr. Tagett had kept them (R. 108). And, as the Government pointed out in its opening brief (p. 5, footnote 6), the record showed that the tablets in question had been prepared eleven months before defendants shipped them to Dr. Tagett, and there was no evidence of their strength when shipped. The verdict of the jury was adequately supported by the evidence.

Respondent has commented on the accuracy of the frog test, by which these tablets were assayed. This test was prescribed by the United States Pharmacopeia, p. 397, and therefore was the one which the Act required be used (R. 72-73, 74, 50, 52). The fact that this test was required because

¹⁵ For corroborating testimony from other sources, see R. 55-56, 87-89, 90, 146.

it was, in expert opinion at that time, the most reliable one known, was made abundantly clear to the jury, by defendants' cross-examination as much as by anything else (R. 52, 74-76, 87, 91, 97-98, 100, 103). The manner and theory of its operation were explained to the jury by a Government pharmacologist (R. 74-77), who was excellently qualified as an expert (R. 70-71). Dr. Chapman, whom as previously noted respondent's counsel had built up as an expert, stated his belief in the merits of the frog test (R. 103). The only suggestion of inadequacy of the frog test came from insinuations of respondent's counsel (R. 53, 69, 83-84, 91, 103), which in the face of the expert testimony must not have impressed the jury.¹⁶ The jury was justified in giving credence to the results of the frog test.¹⁷

III. THE BASIS OF THE DECISION BELOW

Perhaps a few words may appropriately be added regarding the construction of the statute

¹⁶ Respondent was not denied the opportunity to offer proof on this point. The court ruled, when the Government objected to cross-examination on the merits of the frog test, that the defendants had the right to demonstrate it if experience showed the frog test inaccurate (R. 91).

¹⁷ Significantly, defendants did not offer evidence of any assay of the tablets conducted by the cat test which they advocated. We are advised by the Food and Drug Administration that no possibility exists that these tablets, which were assayed at 42%, 48%, and 51% by frog tests (R. 52, 77, 98, 99), would have shown 80% strength or more, as required by the U. S. Pharmacopeia within the 20% tolerance allowed (R. 77, 107), if they had been assayed by the cat test.

upon which the decision below turned. Because of the separate guaranty provision (Sec. 303 (e)), the court read a limitation into Sections 201 and 301 (a), considered together, which would exclude from the penalties of the Act the activating agent of a corporation who is responsible for a violation. As pointed out in our main brief, this would go far to destroy the effectiveness of the statute and is an unnecessary interpretation. But for the guaranty provision such an agent would be liable. It seems unreasonable to hold that Congress intended by the wording of the guaranty to change this situation. A more reasonable approach in the light of the purpose of the Act would be to hold that the true meaning of the guaranty provision is that the guaranty applies when given by the person from whom the article was received, the natural purpose and meaning of the clause "from whom he received" the article. Identification of the recipient was not the Congressional aim. Thus read, concern as to minor employees is obviated—the guaranty would apply to them as well as the dealer.

The same result would be accomplished by construing the words of Section 301 (a), prohibiting the "introduction or delivery for introduction into interstate commerce", etc., as requiring a responsible act or omission, not merely a physical act: *i. e.*, as being directed at the persons whose failure to exercise the care and responsibility reposed in

them by the business organization resulted in the introduction into interstate commerce of the non-conforming goods. So construed the statute would reach the principal, the supervisory officials on whom the business organization bestows the responsibility of seeing that the business conforms to the law, and any minor employees whose acts, performed negligently or in bad faith and hence in violation of the obligation imposed on them, caused the violation of this Act. Acting negligently or in bad faith is in essence an assumption of responsibility even when done by a minor employee since the normal contemplation of authority to act is that the acts will be performed carefully and without wrongful intent. On such a construction, well-intentioned minor employees, whose place in the business organization prevents their knowledge of or authority to prevent the nonconformance of goods, would not be liable. This construction is not inconsistent with the textual requirements of Section 301 (a) since it does not require that Section 301 (a) be given a different meaning in prosecutions under Section 303 (b) than it has in prosecutions under Section 303 (a). Moreover it is reasonable, since it permits the accomplishment of the purposes of the Act. It permits the application of the felony provisions of Section 303 (b) to all persons in the chain of causation who act with intent to defraud or mislead, and of the milder provisions of Section

303 (a) to all persons whose improper exercise of supervisory power or whose negligent exercise of clerical authority directs the chain of causative responsibility to them. Prosecutions under the Act and the predecessor Act of 1906 have not sought to hold others.

CONCLUSION

The judgment of the court below should be reversed and that of the district court affirmed.

Respectfully submitted.

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OCTOBER 1943.

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In the Supreme Court of the United States

OCTOBER TERM, 1942

THE UNITED STATES OF AMERICA, PETITIONER

v.

JOSEPH H. DOTTERWEICH

**MEMORANDUM IN OPPOSITION TO PETITION FOR A
WRIT OF CERTIORARI TO THE UNITED STATES
CIRCUIT COURT OF APPEALS FOR THE SECOND
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In the Supreme Court of the United States

OCTOBER TERM, 1942

No. 717

THE UNITED STATES OF AMERICA, PETITIONER

v.

JOSEPH H. DOTTERWEICH

MEMORANDUM IN OPPOSITION TO PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES CIRCUIT COURT OF APPEALS FOR THE SECOND CIRCUIT.

The Solicitor General, on behalf of the United States, prays that a writ of certiorari issue to review the judgment of the United States Circuit Court of Appeals for the Second Circuit entered December 3, 1942, (R. 282).

The question which the government presents for review by this Court (p. 2 of brief) is:

"Whether the manager of a corporation, as well as the corporation itself, may be prosecuted under the Federal Food, Drug & Cosmetic Act of 1938 for the introduction of misbranded and adulterated articles into interstate commerce."

We respectfully contend that this question sought to be reviewed is not a question at all and certainly has nothing to do with the case at bar. It is in fact a reflection upon the Circuit Court of Appeals for the Second Circuit to insist that such a question exists for

review. It is, and always has been, an accepted rule of law, and may be termed an academic proposition, and existed long before the statutes of the United States. It is part of the Common Law. Of course, a manager of a corporation, as well as the corporation itself, may be prosecuted under a criminal statute if both the corporation and the manager did anything that was violative of the law.

This is on the theory that the manager of any other person who aids, abets or assists in the commission of a crime is a principal. But that is not this case.

The Circuit Court of Appeals in this case (R. 282), upon the proposition we there urged, said the following:

“The foregoing discussion has proceeded upon the assumption that if the statute is applicable to the appellant, it must also apply to a shipping clerk or any other menial employee who was instrumental in causing the forbidden shipment, for we can find no basis in the statutory language for drawing a distinction between agents of high or low rank. We are not, however, to be understood to rule that under no circumstances could an individual conducting a drug business in corporate form be subjected to the penalties of Sec. 331 (a). If an individual operated a corporation as his ‘alter ego’ or agent he might be the principal; *but the evidence hardly went so far as to establish that such was the relationship between the appellant and his corporation and in any event his guilt was not made to turn on any such issue.*” (Italics ours.)

If there was any question to be submitted to this court for review, and we respectfully submit there is none, it should be whether the manager of this corporation, and upon the evidence in this case, may be

prosecuted under the Federal Food, Drug & Cosmetic Act of 1938.

This situation can be summed up in one paragraph, to wit, that the reversal by the Circuit Court of Appeals was because of the evidence in the case and the theory upon which the learned District Court Judge conceived the law to be.

The following occurred in the presence of the jury when the question sought to be determined here was directly brought to the attention of the District Court Judge (R. 291):

"Mr. Fleischman: We will assume that our office boy sent out some stuff from a responsible concern; he takes it off the shelf and he sells it; he has every reason and right to suppose that it came from a very reliable concern, perhaps the most responsible in the country, and he sent it out, and your contention as I get it now—

"The Court: *I think I would be glad to rule that the office boy would be equally guilty.* (Italics ours.)

"Mr. Fleischman: That is a proposition on which you are now ruling?

"The Court: Yes.

"Mr. Fleischman: I will respectfully take an exception."

There were a number of questions submitted to the Circuit Court of Appeals in this case upon which they ruled against us and reversed only because they felt that the manager of a corporation who did not know, and could not know, that a product which had been purchased by the corporation from another large pharmaceutical corporation did not in fact contain the full strength required by the federal law.

It, therefore, might be of some interest to briefly set forth the facts in this case.

The Buffalo Pharmaceutical Co., of which the respondent Joseph H. Dotterweich, is the manager, is a concern employing approximately thirty people. They are not engaged in the compounding of any drugs. They are in fact "jobbers". All that they do is to package the material they purchase in their own containers and their own labels and send it out. In the case of the digitalis which the government speaks of, there were a million pills or tablets purchased and sold in bottles of one thousand to physicians throughout the country. The government inspector picked up but one of these bottles that was not up to standard. There was no proof in this case that any of the other pills or tablets in the many other hundreds of bottles were similarly under standard, nor was there any proof that the pills or tablets in the single bottle in question, and which bottle was half used when picked up from the Doctor, were under standard when shipped. The testimony clearly indicated that many things may happen which would reduce the strength or potency of this drug. Of course, the defendants in this case had no way of proving that in the single bottle, which was the basis of this prosecution, that heat, or light, or lack of refrigeration, or moisture, did not in some way come in contact with this particular bottle so as to cause this loss of strength.

But the legal question presented was whether upon the facts in this particular case the general manager, not even knowing of this shipment because it went through in the regular course of business, could be held

responsible together with the corporation, for the fact that unknown to it, or to him, a single bottle of this product deteriorated or was not up to standard strength. Throughout the case the contention of the government was that the good faith and the honest dealing of the Buffalo Pharmaceutical Company, Inc., or of its manager, or of any of its employees, was not questioned.

It, therefore, presented itself as a question to the appellate court, whether upon this record the general manager of this corporation, who we repeat had no knowledge of this transaction, could be convicted of a misdemeanor.

We respectfully present that the dire results prophesied by the Solicitor General as a result of this case upon other prosecutions, cannot possibly become a fact. There has been a new trial ordered by the Circuit Court of Appeals and upon that trial the question of fact as to whether this manager had any connection with this shipment, can be gone into very fully.

The Solicitor General points out that under the Act of June 30, 1906, 21 USCA Sec. 4, which was the old Pure Food & Drug Act, it was provided that "the act, omission or failure of any officer, agent or other person acting for or employed by any corporation, company, society or association, within the scope of his employment or office, shall in every case be also deemed to be the act, omission or failure of such corporation, company, society or association as well as that of the person." He fails, however, to point out that when the law relating to pure food and drugs was changed, to wit, in 1938, under the statute involved in this case,

that this very provision was omitted. We agree with the argument in the Circuit Court of Appeals by the District Attorney that the reason it was omitted was because there was no necessity for it since the common law covered it, and the act of any person associated with the corporation which was wrong could be punished. But it had to be some act on the part of that individual and he, therefore, had to be a principal.

Where bad faith or evil intent are not necessary proof in a criminal case, in other words, if the crime is one *Malā prohibitum*, there can be no conviction of a person on the theory that he aided or abetted.

It is admitted in this case that the manager acted in good faith himself and did nothing intentionally wrong. So, therefore, how could he be a principal by aiding or abetting, by directly committing any act constituting an offense defined in any law of the United States, or in other words, how could he aid or abet, counsel, command, induce or procure the commission of a crime *Malā prohibitum* of which he, in fact, knew nothing about. Only the person or corporation, which is by law made responsible for the crime, can be prosecuted for the same.

To hold otherwise would mean that the whole theory of the government in this prosecution was wrong. If this respondent is to be prosecuted as a principal, then it seems clear that the requirement of this statute as to serving him with notice to appear for hearing, and the ability of that person to receive a guarantee, would have to be established. But the manager of this corporation, or any other employee, could not receive the guarantee provided in Sub sec. (C) of 21 USCA 333.

and, therefore, was deprived of a protection which is accorded his principal and by which the principal could escape prosecution.

While we do not agree with all of the conclusions reached by the Circuit Court of Appeals, the views expressed by that court on the question which it is claimed there exists in this case for review, are very clear. They are contained in the record on appeal on pages 280, 281 and 282.

We respectfully present that the application for a writ of certiorari in this case should be denied, and when this case is retried, as it must be, a clearer record will be presented for review.

Respectfully submitted,

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U.S. DISTRICT COURT

No. 5

In the Supreme Court of the United States

OCTOBER TERM, 1943

THE UNITED STATES OF AMERICA, PETITIONER,

vs.

JOSEPH H. DOTTERWEICH, RESPONDENT

**ON WRIT OF CERTIORARI TO THE UNITED STATES CIRCUIT
COURT OF APPEALS FOR THE SECOND CIRCUIT**

**BRIEF FOR THE RESPONDENT, JOSEPH H.
DOTTERWEICH**

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**BRIEF FOR THE RESPONDENT, JOSEPH H.
DOTTERWEICH**

By informations filed in April and August, 1940, in the United States District Court for the Western District of New York, the respondent, and the Buffalo Pharmaceutical Company, Inc., were charged in separate counts with violations of the Act of Congress known as the Federal Food, Drug and Cosmetic Act, in that they unlawfully introduced and delivered for introduction in Interstate Commerce a consignment of a drug known as "Digitalis," which shipment consisted of one thousand pills of digitalis, which purported to represent on the label of the container thereof that the tablets were the strength or potency of one and one-half grains, when in fact the pills were not of that potency or strength.

In the second count it was claimed that the said digitalis was misbranded in that it was represented upon the label attached to the bottle containing the said digitalis a statement that it contained digitalis of the potency of one and one half grains and in fact it did not and, therefore, the branding was "false and misleading."

The third information, referred to the introduction into Interstate Commerce, pursuant to the same Act, of a drug which it is claimed was also misbranded; to wit: tablets of cascara compound (Hinkle), which was marked on the label attached to the bottle containing the article and which was "false and misleading," in that the said statement purported and represented that the said article consisted of tablets of compound cascara (Hinkle), which is a drug recognized in the National Formulary under the name "Compound Pills of Cascara (Hinkle)," whereas in truth and in fact the said article did not consist of tablets of compound cascara (Hinkle), in that the said article contained a strychnine sulphate ingredient, which is not included in the formula set forth as the standard for compound pills of cascara (Hinkle pills) in the said National Formulary.

These informations were filed by the United States District Attorney for the Western District of New York, not on his own initiative, but at the request or demand of the Department of Agriculture. We hold this fact to be important and it is not disputed by the Government.

The case came on for trial before the Hon. Harold P. Burke, Judge of the United States District Court for the Western District of New York, and a Jury, and the trial lasted about three days. The Jury's verdict, after having the case under consideration for about eight hours, was one finding the individual Joseph H. Dotterweich, the respondent here, guilty on all three counts of the Informations, and disagreed as to the corporate defendant. An

appeal was thereupon taken by the respondent here to the United States Circuit Court of Appeals for the Second Circuit and the convictions as to him were there reversed. The Government now appeals after obtaining certiorari. The jurisdiction of this Court is not questioned.

STATEMENT

Throughout the trial of this case, and now, the Government has taken the attitude, properly, that there is no question of the good faith of this respondent nor the corporation which was on trial with him in the District Court, but contends that the question of good faith and the fair dealing and the integrity of either the corporation defendant or the respondent here is not pertinent to the issue of whether or not they, or either of them, were guilty of the crime charged. Therefore, at every stage of the case, when it was sought to establish the good faith, honest dealing, integrity and fairness on the part of the defendants, upon objection of the District Attorney who tried the case, the matter was ruled out. This happened numerous times during the trial of the case. A fair illustration is found in the record—R. 291.

"The Court: Do you want to know about the good faith of the Buffalo Pharmaceutical Company?

Mr. Doran: I make no claim of that.

Mr. Fleischman: I started out to say that we will prove that we used the very best stuff—

The Court: I see no need for this argument. It makes no difference if you have some other argument, I will be glad to listen to it. In view of the Statute, no matter what the intentions were, no matter how good their reputation was, it is immaterial. The Statute makes it so."

Arner & Company, the Government's witness, was being cross-examined:

"Q. Based on the evidence that you heard, will you tell me what you or the Buffalo Pharmaceutical Company, under those circumstances, could have done or not have done?

A. I know very well what I would have done. Mr. Doran I object to the question. The question of good faith is not an issue here.

The Court: I think that that is so.

Mr. Fleischman: The witness is awfully anxious to answer it and I think he should. I would like his answer.

Mr. Doran: Not an issue in this case.

The Court: Sustained.

Mr. Fleischman: Very good.

The Court: On the question of good faith, that is not an issue here."

Repeatedly, that same theory was emphasized by the Court to the Jury, to wit: that the question of good faith, integrity and fair-dealing were not an issue to be decided by them.

The knowledge by the defendants, or either of them, as to the actual contents of the articles transmitted in Interstate Commerce, was also ruled immaterial.

The Buffalo Pharmaceutical Company, Inc., is a large pharmaceutical concern doing business in the City of Buffalo in the State of New York. It employs about thirty persons. The corporation does not itself manufacture or compound any drugs. It is just a dealer or a peddler of drugs, purchasing these drugs from the largest of the pharmaceutical houses in the United States and selling them to drugists throughout the United States in smaller quantities. It takes orders for drugs from physicians and when these orders are received by the corporation, its employees do nothing more than to pack these articles and ship them to these customers.

The respondent, Joseph H. Dotterweich, is now the president of the corporation defendant and its General

Manager. There is no proof in this case that he personally gave any instructions with reference to either of the shipments set forth in the informations, except that he admitted, as did the head of the shipping department, that general instructions had been given to the shipping clerk when the concern was organized, and that the shipping clerk used his own previous experience as well as his common sense in the conducting of that department of the corporation. Generally, the instructions then given by the respondent to his employees, that is to say, when the concern was organized in 1937, was that when orders came in and were filled by the manufacturing pharmacists and received from them, they were to be shipped to the person from whom the order was received. Nowhere in the record is it claimed that the respondent knew anything about these particular orders, the basis of these informations, or that he ever met the doctors who sent in the orders, or that he had ever himself solicited any business or even knew the towns where these physicians conducted their professions.

The conviction in the District Court rested upon the testimony of John S. Farries, who was a witness for the Government and an inspector for the Food & Drug Administration, which is one of the Federal Securities agencies. This witness claimed that his job is to travel around the country and pick up from physicians some of the drugs they bought and submit those drugs for test to the department at Washington to ascertain whether or not they contained the necessary strength or potency.

While on that mission, and on October 24th, 1939, he called upon a physician in Homer City, Pennsylvania, and purchased from that physician a small bottle containing Hinkle pills and forwarded that bottle to Washington.

Subsequently this same agent picked up a bottle containing digitalis from Dr. Taggart at Rock Creek, Ohio, in Feb-

ruary, 1940, and that he forwarded that bottle to the department at Washington. After an inspection and analysis by the authorities in Washington, the matter was reported by the Department to the District Attorney for prosecution, upon the ground that the bottle containing Hinkle pills stated on the label thereof that it contained some strychnine sulphate, which the Government contended, under the last edition of the National Formulary, which was not then printed, had been eliminated from the necessary make-up of Hinkle pills. The label on this bottle, it is admitted, contained the statement of all the ingredients of the particular pills, including, of course, the statement that it contained strychnine sulphate. However, the contention of the Government was that even though the label did correctly state just what it contained, it was nevertheless a violation, in that Hinkle pills, as contained in the formula, did not permit strychnine sulphate.

Hinkle pills have for many generations been used by families in America and throughout the world. It was originally a prescription of one Dr. Hinkle, who undoubtedly passed on long before any person now living was born, and while the Government still permitted the name of "Hinkle" for this simple drug, it did not allow the pill to contain the Hinkle formula. In other words, why a Hinkle pill is no longer a Hinkle pill and yet called by the Government a Hinkle pill, no one seems to be able to explain. If the Government did not like the Hinkle formula it could have forbidden its manufacture. To retain the name of Hinkle and have the public believe that it is the pill that they and their forebears have been using for generations, we respectfully contend is not a misbranding by any manufacturer of Hinkle pills but a misbranding by the Government. The Government admitted that one could send in Interstate Commerce pills containing the old Hinkle formula, which, of

course, contains strychnine sulphate, without violating the law, but as we get it, the Government claims that no one has the right to use the word "Hinkle" on the label, even though it does contain the Hinkle formula, and even though that label contains a correct description of its ingredients. In other words, the shipment into Interstate Commerce of tablets of Cascara Compound with strychnine sulphate is not forbidden, and although the ingredient strychnine sulphate is not removed, but the true name of the formula, viz., "Hinkle", is forbidden to be used. The information charges that such an act on the part of whœvr was responsible for it, was "false and misleading" to a purchaser of Hinkle pills. However, not a single purchaser of Hinkle pills or any other person was called as a witness to testify that he was fooled or misled by the purchase of this bottle, or that he supposed that it did not contain strychnine sulphate, when as a matter of fact it did.

The informations with respect to the digitalis were also based upon the recommendation of the department in the first instance. In other words, the prosecution in this case did not originate with the District Attorney of the United States; it originated with the Department of Agriculture, or, as it is now called, the Food & Drug Administration.

When Mr. Farris, the Government agent, obtained the bottle of digitalis from Dr. Taggart, which had been purchased by Dr. Taggart from the Buffalo Pharmaceutical Company, and which it was stipulated by the defendants in the case traveled in Interstate Commerce to Dr. Taggart, and forwarded that article to the Department at Washington, it was there analyzed and it was found that the strength or potency was less than one half of the potency marked on the label. The digitalis as well as all other drugs sold by the defendant corporation in this prosecution was bought by it from Arner & Company, a very large and responsible manufacturing pharmaceutical concern.

The basis of the prosecution here was for both misbranding and adulteration.

It was admitted by the Government that no notice, pursuant to Section 335 of Article 21 of the Food & Drug Act, had been given by a representative of the department to the Respondent here, but that such a notice was given to the defendant corporation, the Buffalo Pharmaceutical Company.

The question which we sought to raise was, did the loss of potency occur and if so, how and where, or was it of a lower strength or potency when shipped. In other words, it was the contention of this respondent and of the corporation defendant that if this half-filled bottle of digitalis which had been frequently opened and which was taken from the shelf of Dr. Taggart, showed that its contents had but half the strength claimed for it upon the bottle, there was no proof submitted as to where this loss of strength took place. Digitalis is a type of drug which loses its potency or strength under many conditions. The Government has completely failed to eliminate the possibility of it having lost its strength or potency through the failure or neglect of parties other than the corporation defendant here. Since this is a criminal case, it was necessary for the Government to prove beyond a reasonable doubt that the loss of strength or potency of digitalis was caused through some act of commission or omission of the defendant corporation.

It was the claim of this respondent upon the trial and upon subsequent appeals to the Circuit Court that as an employee he could not be held liable under the circumstances under any conditions, except if he wilfully and knowingly did something that was wrong, that is to say, he either did something he should not have done or did not do something that he should have done; that the loss

of potency in digitalis was not due to any neglect on his part and that neither he nor the corporation knew or could have known of the condition that existed or could have learned of it in any way by any known tests; that the test as to potency as used by the Government was useless and unfair—that the so-called "frog" test was not a proper test and that the only fair test was the "cat" test, which contention has since been approved by the Government as the official test since the trial of this case; that the respondent was under no circumstances in this case liable even if the corporation could be in some way held liable; that the loss of potency occurred subsequent to the shipment in Interstate Commerce by conditions over which neither the respondent nor the corporation had any control; and, lastly, that the failure to convict the corporation defendant, the owner of the business, did not allow the conviction of the respondent individually for a crime which is not *malum in se* but *malum prohibitum*.

This case is very important to this respondent in that he is a man who the Government admits acted in good faith and complete fairness and integrity and who has been convicted of three misdemeanors—crimes against his own Government. This not only affects his personal standing in the community, of which he has been heretofore an honored member, but his standing in the business world as well. He is now looked upon as one who adulterates and misbrands his drug products, and, therefore, a man without honor in his business dealings, a situation which will destroy this large business established by honesty and perseverance.

POINT ONE.

It is necessary under the Act, and an indispensable requisite, that notice as required by Section 335 should be given by the Government to this respondent before the beginning of any prosecution.

It is conceded by the Government that the respondent was not served with notice of any hearing which affected him, as required by Section 335 of the Act, before the matter was reported by the Secretary to the United States Attorney. This important question, raised many times upon the trial, was whether such a notice is necessary before the institution of a criminal prosecution by the United States Attorney. The answer has not been given by the Courts since the new Act of 1938.

It is quite important that we have before us the old Act, that is to say, the Act prior to 1938, as well as the present Act, and to simplify the argument we have set forth the old Act and the present one side by side.

Old Act—Section 11—Title 21:

“The examinations of specimens of food and drugs shall be made in the Bureau of Chemistry in the Department of Agriculture *** and if it shall appear from any such examination that any of such specimens is adulterated or misbranded, the Secretary of Agriculture shall cause notice thereof to be given to the parties from whom such sample was obtained. Any party so notified shall be given an opportunity to be heard *** and if it appears that any of the provisions of said sections have been violated by such party, then the Secretary of Agriculture shall at once certify the facts to the proper United States District Attorney.”

NEW ACT—Section 335—Title 21:

“Before any violation of this chapter is reported by the Secretary to any United States Attorney for institution of a criminal proceeding, the person against whom such proceeding is contemplated shall be given appropriate notice and an opportunity to present his views either orally or in writing, with regard to such contemplated proceeding.”

Prior to the adoption of the new Act of 1938, the cases construing Section 11 of Title 21, which is the section which required notice to be given, were at variance, but in 1911 this Court, in the case of United States vs. Morgan, reported in 222, U. S. 274, determined that the notice and hearing provided for in that Act was not a condition precedent to the commencement of a prosecution. This Court, in that case, speaking through Mr. Justice Lamar, emphasized that if it had been the intention of Congress to make the giving of a notice a condition precedent, "the Statute would have required that a hearing should be given to all persons charged with the violation of the Act and not merely to those from whom the sample was received." That decision, therefore, settled the law upon that question. Under the old Act there was a requirement that where the proceeding was instituted in the first instance by the Secretary of Agriculture, who then had this character of prosecution in charge, that then the Secretary of Agriculture should give notice thereof to the parties from whom the sample was obtained. Under the old Act, upon the facts as we have them in this case, the notice would have to be served by the present bureau upon Dr. Taggart, who is the physician in the rural community to whom these pills were sold.

There was no change by Congress of the Food & Drug Act after the decision of United States vs. Morgan, *supra*, until the adoption of the present law by Congress in 1938. In this new law Congress used the precise language of Section 11 that Mr. Justice Lamar in the Morgan case said it should use if it wanted to make notice a condition precedent. What stronger proof can there be of legislative intent?

In the new Act notice was no longer required to be given to the person from whom the sample was received, but to the person against whom the proceedings were contem-

plated. One of the reasons for the requirement of the notice is explained by Section 336 of the present law, which in substance states that if the Secretary is satisfied that the offense was a minor one, no further action need be taken. This is understandable because where the law, as here, is arbitrary, and creates a crime which is *malum prohibitum* and only that, the Court should not be asked to stamp a man a criminal where the same salutary effect could be obtained by a mere warning.

Then again there was before Congress undoubtedly the same question as the one before the Court in the Morgan case—should the minor employee, the shipping clerk in a very large concern, the wrapping clerk, the boy who takes the packages to the post-office—in other words, the person who actually introduces into Interstate Commerce the misbranded product be held criminally responsible, even though the contents of the package are unknown and unascertainable to him? If, therefore, the respondent or any other employee of a corporation, against whom such proceedings were contemplated, were to receive notice, it would give him an opportunity to appear before the Secretary or his representative and point out that in no way did he have anything to do with the transaction in a criminal capacity.

In 1939, almost immediately after the passage of this new law, in "Law and Contemporary Problems," which is a publication of the School of Law of Duke University, there was an article entitled "The Enforcement Provisions of the Food, Drug & Cosmetic Act," written by Frederic P. Lee, who was the Government's counsel to the United States House of Representatives and the United States Senate and special counsel to the Secretary of Agriculture and a professor of Statute Law at Georgetown University

Law School. In volume 6 on page 74 he calls attention to the very matter with which we are concerned. He says:

"The new Act specifically provides that before any violation is reported by the Secretary of Agriculture to any United States Attorney for the institution of a criminal proceeding, the person against whom the proceeding is contemplated shall be given appropriate notice and opportunity to present his views, either orally or in writing, with regard to the contemplated proceeding." "The old Act also provided for such a hearing, although the language was ambiguous and was construed by some courts as requiring administrative hearings preliminary to trial for condemnation as well as criminal proceedings. Further, the new Act adopts the administrative construction previously placed on the old Act."

"Under the old Act the United States Attorney had the duty of instituting criminal proceedings upon report of any violation by the Secretary of Agriculture. He was bound to accept the findings of the Secretary and not make any other independent investigation to satisfy himself. However, the United States Attorney could also under other general provisions of the law, on his own initiative, institute proceedings irrespective of receipt of any report by the Secretary of a violation. In such event the Statute required no preliminary administrative hearing. The new Act omits the mandatory duty of the United States Attorney to prosecute at the Secretary's directions. In consequence the District Attorney has discretion in all instances as to whether criminal proceedings will be instituted. The right to a preliminary administrative hearing still exists only when the Secretary reports the violation. *** Nevertheless the administrative hearing constitutes a real protection against unfounded criminal prosecutions in food and drug cases, for it is only rarely that the United States Attorney institutes such prosecutions otherwise than at the instance of the Secretary."

In 1942 a book entitled "A Treatise on the Law of Food, Drug & Cosmetics" was published. It was written by Harry Aubrey Toulmin, Jr., J. D., Litt. D., L. L. D. So far

as we know this is the first publication on the law of Food, Drugs and Cosmetics since the new law. On page 609 of that publication is an article entitled "Monograph Prepared by Food & Drug Administration Officials for Guidance in Administrative Procedure," prepared under the direction of Masten G. White, Solicitor, Ashley Sellers, Head attorney Office of Solicitor, and Nathan D. Grundstein, Research Assistant Office of the Solicitor.

On page 737 of the book entitled "The Law of Foods, Drugs & Cosmetics," which is page 277 of the Monograph, the question we are concerned with here is discussed as follows:

"The present Food, Drug & Cosmetic Act has not sought to change the administrative character of the hearing. The text of Section 305 does not contain any reference to the word 'hearing,' stating only that when the person against whom a criminal proceeding is contemplated 'shall be given appropriate notice and an opportunity to present his views, either orally or in writing, with regard to such contemplated proceeding.' Such a procedure is required only 'before any violation of this Act is reported by the Secretary to any United States Attorney for institution of a criminal proceeding,' *with the inescapable inference, therefore, that Section 305 was intended to overrule to this extent the effects of United States vs. Morgan on the jurisdictional aspects of the pre-prosecution proceeding.*' (Italics ours.)

The author of that book, on page 81 of that volume, himself agrees with this contention and refers the reader for a further discussion of the subject to the Monograph aforesaid.

We want to emphasize that it would have been of considerable benefit to this respondent to have received this notice of contemplated action, because under Section 333, sub-division C, Title 21, he could have proved to the Secretary that he was protected. That section reads:

"No person shall be subject to the penalties of subsection A of this section for having received in Interstate Commerce any article or delivered it, or preferred delivery of it, if such delivery or proffer was made in good faith, unless he refuses to furnish on request of an officer or employee duly designated by the secretary the name and address of the person from whom he purchased or received such article and copies of all documents, if any there be, pertaining to the delivery of the article to him."

It appears clear, in the present case, from the testimony of the representative of the Secretary, that no notice was given to the respondent (R-115-116) and that no request was made for any information and that the agent knew that he could have obtained this information had he asked for it (R. 118). It is to be noted particularly that the question of notice pursuant to Section 335 of Title 21 was intended to be given to the parties who it was contemplated would be made defendants in a criminal action because notice was given by the Department to the corporation defendant.

POINT TWO:

The respondent was the agent of the defendant corporation and some wrongful act on his part must be shown.

It was claimed by the Government that the respondent was general manager of the corporation and for that reason and because the corporation of necessity can only act through its officers or manager, the respondent could be held responsible.

This claim, in our opinion, brought about the conviction in the District Court of this respondent. This proposition was put squarely to the jury by the Court in its statement that the humblest employee, regardless of intent, could be prosecuted and convicted under the law. In view of such a statement the jury could well feel bound to convict a more important officer.

We refer to pages 62 and 63 of record:

"Mr. Fleischman: I started out to say that we will prove that we used the very best stuff—

The Court: I see no need for this argument. It makes no difference. If you have some other argument I will be glad to listen to it. In view of the Statute, no matter what the intentions were; no matter how good their reputation was, it is immaterial. The Statute makes it as it is.

Mr. Fleischman: As we stand here we have an individual, the defendant here, and I think we have the right to prove the good faith as we stand now.

The Court: I cannot follow your argument and I cannot see the difference between the individual and the corporate business.

Mr. Fleischman: We will assume that our office boy sent out some stuff from a responsible concern. He takes it off the shelf and sells it. He has every reason and right to suppose that it came from a very reliable concern, perhaps the most responsible in the country, and he sends it out, and your contention, as I get it now—

The Court: I think I would be glad to rule that the office boy would be equally guilty.

Mr. Fleischman: That is the proposition on which you are now ruling?

The Court: Yes."

The evidence in this case shows no directions or instructions by the appellant to anyone as to this particular shipment or as to any other particular shipment (Record 129.) The corporate defendant deals in a great many pharmaceutical products and the items named in the information in this case are extremely small as compared with its volume of business. As in any other large concern, the general manager issued general instructions regarding orders, inventory, shipments, etc., to his fellow employees. It is nowhere claimed, in fact it is repeatedly denied by the Government, that Mr. Dotterweich gave any instructions to carry on any unlawful activity. The crime, if there was

a crime, was clearly *malum prohibitum* and was committed by the corporation, not its employees. We have repeatedly contended that the law does not impose the same liability on the agents as it does on principals in cases *malum prohibitum*. The best proof of this lies in the fact that the law provides a protection to the principal by granting him immunity from prosecution if he produces a guarantee. No such guarantee can run to an employee. Can it be argued that the Legislature intends to be harsher with the agent than the principal? It is admitted by the learned Attorney General that it was not necessary for the respondent to secure a guarantee from the seller of the product to the corporation, and it is also admitted that there was not such a relationship between the respondent here and the seller of the merchandise as would permit the respondent to ask for a guarantee for himself. This guarantee applies only to the purchasers, and this respondent had no dealings with the seller.

It is interesting to note that prior to the Drug Act of 1938, there was a section (Section 4) in this very law which provided that the act of the corporation was also the act of the individuals composing that corporation, and that this very section was, under the laws of 1938, when the new drug law went into effect, completely deleted. Why? It seems to us that it was deleted, first, because if the crime was *malum in se*, it was unnecessary to have that clause, because under the common law, the officers of a corporation or its employees who participated in the doing of something which was wrong, were clearly guilty with the corporation, and if the offense was *malum prohibitum*, Congress did not want the employees punished for the doing of things against which they had no protection.

The learned Attorney General argues in his brief, page 33: "We believe, however, that the Statute should be con-

strued to relieve clerks of liability in proper cases, since it is inconceivable that Congress intended to spare clerks who acted with intent to defraud or mislead or who negligently and contrary to instructions acted so as to cause a violation of the Act."

We have no fault to find with that thought on the part of the Attorney General. We agree with him that it is the law and should be the law if it is not, that every employee of a corporation should be held responsible for a crime of the corporation where that employee knows that the actions of the corporation are criminal. In other words, it is a crime *malum in se* and the clerk participates, aids and abets in the commission of that crime. However, we believe it to be most absurd to say that Congress intended to hold an employee responsible for an offense which that employee, no matter how careful, no matter how honest, no matter how decent and law-abiding he may be, could not by the most diligent effort know about.

The learned Attorney General says in his brief that it must be left to the good judgment of the administrative officer to determine who is to be prosecuted. We are in complete disagreement with that contention. Are we to depend for our liberty and our honor upon the caprice or, shall we say, the kindness or the particular liking for us by any district attorney? Even assuming that he is the present occupant of that respected office, who in our opinion is a fine gentleman of unquestioned honor and integrity. Tomorrow there may be a different kind of a prosecutor and where it is discretionary with the District Attorney as to who to prosecute, it may be that that particular district attorney has a dislike for the vice president of a corporation and a strong liking for the president of the corporation, and since he can designate who shall be held responsible for an offense *malum prohibitum*, he may prosecute whichever of the officers he does not like.

The charge here is not conspiracy. It cannot be conspiracy, because conspiracy requires intent. Yet this respondent is charged as a principal because he was an employee of the corporation.

The appellant's brief is in error in its footnote on page 26. If the respondent had ordered this digitalis, knowing that it was not up to proof, he would be guilty even if he was the office-boy. That contention is not disputed by the respondent. Once we have knowledge that a thing is wrong, then we leave the field of an offense *malum prohibitum* and enter the field of *malum in se*. We know we are doing something which is wrong and wicked and there it makes no difference what position we occupy with the corporation, important or otherwise, we are a part of the guilty scheme—we are conspirators in the doing of a guilty act. All of that is not present in a case of where we had no intent to do wrong, could not know that it was wrong, and even by the most diligent efforts could not ascertain that it was violative of any section of the law. Surely it is clear to the Government that this respondent did not know that this drug was misbranded. Even if it was, it was not possible for this respondent to take each item as it came from a responsible pharmaceutical concern and himself make some test, even if there was such a test. It stands to reason that it is impossible to make a test upon each pill of the thousand that go into a bottle which sells for \$1.60, and yet it is the Government's contention that if any one of those pills, for whatever reason, fell below its marked potency or strength, that a crime is committed.

In the recent case of the Direct Sales Company vs. United States, 63 U. S. Supreme Court, 1265, which has no connection with this respondent or with the corporation with which the respondent is connected, except that they are both located in the City of Buffalo, New York, the convic-

tion was sustained upon the theory that the corporation knew or should have known that the large quantity of morphine it was selling to a physician in a very small community, must have given it notice that its product was being used for illegal purposes. This is understandable; this is not *malum prohibitum*. This character of sale in these very large quantities of a very dangerous drug to a physician in a small community should have put the corporation on its guard as to the uses to which the commodity was to be put, and Mr. Justice Rutledge, speaking for this Court, in our opinion correctly stated that the corporation there had notice of what was being done with its drugs was illegal, and yet in that case no individual member of that corporation was held liable.

In the case of Bourdeau, Special Assistant Attorney General, against McDowell, reported in 256 U. S. 465, Mr. Justice Brandeis, dissenting with Mr. Justice Holmes, had occasion to use this pregnant thought, which we respectfully submit applies in this case:

"Respect for the law will not be advanced by resorting in its enforcement to means which shock a common man's sense of decency and fair play."

As we view it, holding an employee responsible in the sale of a misbranded product over which he had no control, and the contents of which were completely unknown to him, without more, would certainly shock a common man's sense of decency and fair play.

The Government's contention is that while it is true that now and then an innocent man might be convicted, one who had no knowledge and could not have any knowledge of any wrongdoing, yet the law reads that intent is not necessary and that person must be convicted.

That theory brings us back to the Biblical days when one was punished for a crime consisting of a wrongful thought.

and where one possessed such a wrongful thought it was necessary for him to sacrifice a goat or a sheep or a ram, but an animal without a blemish (otherwise it was not acceptable) and offer him as a sacrifice upon the altar of his God for having sinned without intent, evidently the Attorney General thinks that some such law must be resurrected, that a goat was necessary to be sacrificed, and so they selected this case, and we must agree that they thought they did select an animal without a blemish, an upright, decent and honest citizen, the respondent here, as the sacrifice. But until and unless that theory of crime and punishment is again recognized in civilized communities, it cannot be the law that an innocent employee of a large corporation can be held liable for a crime which is *malum prohibitum* and in the doing of which the respondent had no knowledge or intent or purpose to in any wise do any act contrary to the laws of this country, and yet the unblemished record which his forebears have handed down to him through the generations no longer can be handed down to the future generations, because without knowledge and without intent and with no purpose to do wrong, a bottle of drugs is sent in Interstate Commerce by someone other than the defendant, which in the course of that travel, for some reason unknown to anybody, loses its potency, and which makes the respondent an employee of the corporation guilty of misdemeanors against the Government of his own country.

POINT THREE.

The facts are as consistent with innocence as with guilt.

The respondent has consistently urged that the Government has failed to prove beyond a reasonable doubt that the digitalis found in the possession of Dr. Taggart was of a

lesser potency than labeled when it was shipped by the corporate defendant.

The defendant corporation purchased these drugs from a very large and responsible pharmaceutical concern, Arner & Company. There was no connection between Arner & Company and the defendant corporation in any way except that as seller and buyer. Arner & Company sold to the defendant corporation the shipment in question, to wit: a total of 1,500,000 tablets of digitalis. This is a comparatively small order. Arner & Company was the sole seller of this product to the defendant corporation. If the Government discovered a single bottle of Arner & Company product of digitalis, containing less potency or strength than was marked upon that bottle, they had the right to investigate the books of the defendant corporation and find out to whom the drug had been shipped. The duty of the Government would be in that case, in view of the character of the drug, to go to every doctor to whom such drug was sold and examine the supply of digitalis. They would further advise the defendant corporation, an innocent purchaser of this drug, of the condition of the drug and have it call the drug back from those to whom it was sold. Is it possible that the Government of the United States, upon discovery of this drug marked one and one-half grains, and actually containing only one-half of that strength, would rest upon what they found in a single opened and half used bottle? We charged upon the trial that if the representative of the Government did that they would be guilty of criminal negligence, and we mean just that. On the other hand, we had no way of proving that, as a matter of fact, the Government's agents did not go to a great many other doctors to whom we sold this drug and found the same product sold at about the same time and when tested found that it contained exactly what it was sup-

posed to contain. If that were the case it would then be clear that the bottle of digitalis, which was found in the possession of Dr. Taggart, had by reason of some external condition reduced its potency, and that, therefore, when it left the factory of Arner & Company and was shipped to the defendant corporation and by it introduced into Interstate Commerce, had its full potency.

Many different elements may cause the reduction in the potency of digitalis--heat, light, lack of refrigeration, moisture and some other matters that the experts are unable to determine. The experts agreed that there is some such thing that causes a loss of potency. The bottle of Dr. Taggart had been opened. If the doctor prescribed tablets over a period of time, approximately 250 times, it certainly was not kept refrigerated and nobody paid any particular attention to its being kept in a cool place where neither heat nor light would affect it, and evidently in some way some of these things that do affect the potency of digitalis did affect this bottle, so that when the inspector came and purchased the bottle from the doctor, it did not have the full strength or potency as labeled.

The testimony through the trial on the question of what causes deterioration is most illuminating, or maybe we shall say is most lacking in illumination. The first Government expert Mr. Braun, to whom these products were sent, finally ended up his examination (Page 56 Record):

"Q. Let me make it simple. Do you, as a matter of fact, tell us from your experience as an expert that moisture does have an affect on the potency of digitalis?

A. To tell you the truth, I never worked on deterioration of digitalis. I am not a fit witness on that so far as that is concerned."

This witness was followed by one Lloyd C. Miller, who does the analyzing for the Government when Mr. Braun is

not present, and his contention was that the only thing that will cause digitalis to lose its potency is "cooking." (R. 88.) This witness calls the U. S. Pharmacopeia, the Bible of the profession and "we have to follow it." (R. 92.) "It is prescribed by the Act under which we work, and we cannot pick up any other method that we might think was almost as good or might be easier. We have to follow that one." (R. 72). That sounded very well to the jury. It was his contention that there was no other test for the potency of digitalis than the "frog" test. He had never heard of the "cat" test. As a matter of fact, he wanted to know from us whether we were talking about the "cat's eye" test, (R. 90-91), and finally ended up by saying that he did not know what causes the loss of potency in digitalis other than "cooking." It was his claim that moisture did not do it. It was his claim that refrigeration did not do it and the only thing that would do so would be "cooking." It was very evident that Dr. Taggart did not do any "cooking." Everything seemed to have gone well with this expert and his faith in the Bible of the chemical profession was sublime until his attention was called to the fact that the Bible of the fraternity, on page 137 of the United States Pharmacopeia, it says: "Storage to preserve powdered digitalis in waterproof and air-tight containers and protect it from light."

He was then asked why that was put into the United States Pharmacopeia and his reply was:

"A: Just a precautionary measure. I don't know why they are required, but I heard a lot of manufacturers complaining about it" (R. 92.)

Just previous to that he stated that he didn't care what the manufacturers complained about it and that if the National Formulary and the Pharmacopeia says that is so, that's all there is to it. The attention of this expert was then called to the fact that he himself, when sending

the specimens from Washington to Dr. Chapman at Baltimore, sent them refrigerated, and his reply was that he did not recall having given such testimony.

The only real expert called by either side was Dr. Chapman. He is a teacher of pharmacology at the University of Maryland. The specimen sent to him, which was obtained from Dr. Taggart, was below the potency, but he stated that merely meant that this particular bottle had lost its potency. Dr. Chapman stated that he believed in the "frog" method of analyzing digitalis, and even so good an expert as he was wrong, because he had hardly finished testifying before the Government changed the method of assaying digitalis from the "frog" method to the "cat" method. During this entire trial every expert for the Government belittled and laughed at the "cat" method as a test of digitalis.

In short, the failure of the Government agents to produce other samples which they must have traced, the confusion among the experts as to the proper tests for the potency of digitalis, and the apparent likelihood of external forces causing a reduction in potency present serious doubts as to where the deterioration occurred. It surely is not established beyond a reasonable doubt that the digitalis was under strength when it was shipped by the corporate defendant.

It is, therefore, respectfully submitted, that the judgment of the Circuit Court of Appeals be affirmed and that the informations filed against this respondent Joseph H. Dotterweich be dismissed.

ROBERT J. WHISSEL,
Attorney for Respondent, Buffalo, N. Y.

SAMUEL M. FLEISCHMAN,
Of Counsel.

September, 1943.

No. 5

In the Supreme Court of the United States

OCTOBER TERM, 1943.

THE UNITED STATES OF AMERICA, PETITIONER,

v.

JOSEPH H. DOTTERWEICH, RESPONDENT.

**ON WRIT OF CERTIORARI TO THE UNITED STATES CIRCUIT
COURT OF APPEALS FOR THE SECOND CIRCUIT.**

**PETITION FOR REHEARING BY
JOSEPH H. DOTTERWEICH.**

No. 5

IN THE

Supreme Court of the United States

OCTOBER TERM, 1943.

THE UNITED STATES OF AMERICA, PETITIONER,

v.

JOSEPH H. DOTTERWEICH, RESPONDENT.

ON WRIT OF CERTIORARI TO THE UNITED STATES CIRCUIT COURT OF APPEALS FOR THE SECOND CIRCUIT.

PETITION FOR REHEARING BY JOSEPH H. DOTTERWEICH.

ROBERT J. WHISSEL, on behalf of Joseph H. Dotterweich, respondent, petitions the Court to grant a rehearing in this case.

It is submitted that the petition should be granted for the following reasons:

1. That the Court overlooked the importance and the far reaching effect that this decision, upon the peculiar facts of this case, would have in creating the liability of

employees and officers of a corporation. In the facts of this particular case the Court gives no means by which Joseph H. Dotterweich, the defendant-respondent, could protect himself from absolute liability, even though the same conditions reoccurred, as in this case, although all agree that he acted in good faith and was innocent. Assuming that the defendant had been engaged in war efforts in the service of the United States, the same result, in the particular facts of this case, could have happened.

Your petitioner believes that where the statute is not clear as to who should, or should not be held liable, as in this case, that the liability should not be passed upon the individual defendant, as an innocent employee or officer of a corporation, which is not the manufacturer, but only the jobber, and where the individual did nothing wrong.

2. The Court must have overlooked the fact that the defendant corporation was not the manufacturer, which your petitioner believes is one of great importance in determining where the liability in this particular case should have been limited. Mr. Justice Frankfurter, on page five of the opinion in this case, points out in foot note 2:

"In describing the penalty provisions of Sec. 303, the House Committee reported that the Bill 'increases substantially the criminal penalties which some manufacturers have regarded as substantially a license fee for the conduct of an illegitimate business'. H. Rep. No. 2139, 75th Cong., 3d Sess. p. 4."

This report refers to some manufacturers, and not to the jobber, which would be Buffalo Pharmaceutical Company, Inc., and which Company was not convicted and, therefore,

the construction goes further in holding an employee of the corporation, which was merely a jobber, and not a manufacturer, and which was not convicted. This seems to be beyond the intent of the House Committee and no such circumstances could have been discussed as in this case. Both the reversing and dissenting opinions state that it would be too treacherous for this Court to define, or even to illustrate by way of illustration, the class of employees which stand in such a responsible relation. However, your petitioner refers to pages 62 and 63 of the record:

"Mr. Fleischman: I started out to say that we will prove that we used the very best stuff—

The Court: I see no need for this argument. It makes no difference. If you have some other argument I will be glad to listen to it. In view of the Statute, no matter what the intentions were, no matter how good their reputation was, it is immaterial. The Statute makes it as it is.

Mr. Fleischman: As we stand here we have an individual, the defendant here, and I think we have the right to prove the good faith as we stand now.

The Court: I cannot follow your argument and I cannot see the difference between the individual and the corporate business.

Mr. Fleischman: We will assume that our office boy sent out some stuff from a responsible concern. He takes it off the shelf and sells it. He has every reason and right to suppose that it came from a very reliable concern, perhaps the most responsible in the country, and he sends it out, and your contention, as I get it now—

The Court: I think I would be glad to rule that the office boy would be equally guilty."

Mr. Fleischman: That is the proposition on which you are now ruling?

The Court: Yes."

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Accordingly, your petitioner believes that this is exactly what the lower court did when it stated that it would be glad to rule that the office boy would be equally guilty. This statement was made during the early part of the trial before the jury and seems to be exactly what the Court says the judiciary cannot do.

3. To leave the prosecution of these matters in the hands of prosecutors and their assistants throughout the country, in your petitioner's opinion, would be discriminatory in that they could prosecute whoever they desired as an officer or employee of a corporation. For instance, if they did not like the President, but did like the Vice-President, they could prosecute the President or even the Treasurer, General Manager or other employee. It seems that the Court overlooked such discrimination as present in this case, and also that it is for Congress to decide who is to be criminally prosecuted and not have such powers delegated to the prosecutors and their assistants all over the United States as to what each individual prosecutor believes who should be prosecuted.

Buffalo Pharmacal Company, Inc., purchased digitalis tablets from The Arner Company, Inc., labeled by it 1½ grain digitalis tablets and manufactured for Buffalo Pharmacal Company, Inc., the Buffalo Pharmacal Company, Inc., using the same term as to strength on its label in repackaging the same tablets. Buffalo Pharmacal Company, Inc., also purchased tablets Cascara Compound, Dr. Hinkle, which was on the label from Norwich Pharmacal Company, and which also was stated by Buffalo Pharmacal Company's label as Cascara Compound with the word

"Hinkle". Now the strength of the digitalis tablets, as stated on the label, and the use of the word "Hinkle" on the Cascara Compound were the foundations of the informations. Still the Government failed to make parties defendant, the manufacturers of these articles, which knew the business and the transactions from past experience for years and the kind of business the Buffalo Pharmaceutical Company, Inc., dealt in and, therefore, in the opinion of your petitioner, discriminated by leaving out the very persons, *the manufacturers*, which if any, should have been brought in as parties defendant, and nevertheless, although the Buffalo Pharmaceutical Company, Inc., was not found guilty, still Dotterweich, a good reputable citizen, who acted in good faith, was found guilty.

When arguing before this Court, the Solicitor General stated that Section 333(c) of Title 21, Foods and Drugs, U. S. C. A., did not refer to the violations in question. The petitioner calls the Court's attention to that section:

"(c) No person shall be subject to the penalties of subsection (a) of this section, (1) for having received in interstate commerce any article and delivered it or proffered delivery of it, if such delivery or proffer was made in good faith, unless he refuses to furnish on request of an officer or employee duly designated by the Administrator the name and address of the person from whom he purchased or received such article and copies of all documents, if any there be, pertaining to the delivery of the article to him".

This means that anyone who acts in good faith, which seems to have been the intent of Congress, and stated in so many words, should not be subject to the penalties of Subsection 333(a). Your petitioner points out this section

as tending to show that the good faith of a person, especially under the circumstances and facts of this case, is an important factor in determining the innocence of such person.

Reading this section of the law as passed in conjunction with the Committee's report, as stated in reason 2 of this petition, would show an intent on the part of Congress not to hold the defendant Dotterweich guilty on the facts of this case—first, because only the penalty provisions, and not the persons to whom they apply, were increased and these, as reported, because *some manufacturers* regarded the penalty as a license fee; and second, who are the "*some manufacturers?*" Surely not the Buffalo Pharmacal Company, Inc., a jobber with a good reputation, and not found guilty of any crime, and certainly not Dotterweich, an innocent employee of the Buffalo Pharmacal Company, Inc., who did nothing wrong.

4. Your petitioner further states to this Court that there can be no confusion in construing the liability of this defendant, depending upon the question of agency. Purely, on a question of agency; if the Buffalo Pharmacal Company, Inc., a jobber corporation, was not found guilty, its employee or agent, who, without doing any overt acts and with innocence and good faith on his part admitted, should not be held liable.

The liability of the defendant Dotterweich in this case could not be held on the theory that he aided or abetted in the commission of a crime, when, in fact, it is admitted that he neither did anything wrong or knew of anything that was done wrong, and that, in fact, he acted in good

faith, and further, that he could not have aided or abetted in the commission of a crime committed by Buffalo Pharmacal Company, Inc., when in fact it had not been found guilty of any crime.

If the Legislature intended to make this defendant Dotterweich, the respondent herein, liable, it could have easily included him in so many words in the statute.

Under the peculiar facts of this case, where the defendant has been found guilty, your petitioner states that the Government could not have been harmed by finding the defendant Dotterweich not guilty. A statute could very easily have been passed if it intended to hold such persons as the defendant Dotterweich liable in the particular facts of this case, and further, if Dotterweich had committed a crime *malum in se* and not *malum prohibitum*, the common law would have covered his violation. In any event, however, should this individual Dotterweich be convicted of a crime, where his innocence is admitted, his good faith, the honest dealings and fairness of the corporation and himself also admitted, it is mindful to your petitioner of the statement of that great judge, the Late Benjamin Cardozo, in his book "Growth of the Law", where he says:

"Judges march at times to pitiless conclusions under the prod of a remorseless logic which is supposed to leave them no alternative. They deplore the sacrificial rite. They perform it; none the less, with averted gaze, convinced as they plunge the knife that they obey the bidding of their office. The victim is offered up to the gods of jurisprudence on the altar of regularity".

WHEREFORE, it is respectfully requested that a re-hearing be granted.

Respectfully submitted,

ROBERT J. WHISSEL,
Attorney for Joseph H. Dotterweich, Respondent,
1927 Liberty Bank Building,
Buffalo, New York.

I CERTIFY that this petition is presented in good faith,
and not for delay.

ROBERT J. WHISSEL,
Attorney for Joseph H. Dotterweich, Respondent.

December, 1943.

SUPREME COURT OF THE UNITED STATES.

No. 5.—OCTOBER TERM, 1943.

The United States of America, Petitioner,
vs.
Joseph H. Dotterweich. } On Writ of Certiorari to the
United States Circuit Court
of Appeals for the Second
Circuit.

[November 22, 1943.]

Mr. Justice FRANKFURTER delivered the opinion of the Court.

This was a prosecution begun by two informations, consolidated for trial, charging Buffalo Pharmacal Company, Inc., and Dotterweich, its president and general manager, with violations of the Act of Congress of June 1938, c. 675, 52 Stat. 1040, 21 U. S. C. §§ 301-392, known as the Federal Food, Drug, and Cosmetic Act. The Company, a jobber in drugs, purchased them from their manufacturers and shipped them, repacked under its own label, in interstate commerce. (No question is raised in this case regarding the implications that may properly arise when, although, the manufacturer gives the jobber a guaranty, the latter through his own label makes representations.) The informations were based on § 301 of that Act (21 U. S. C. § 331), paragraph (a), of which prohibits "The introduction or delivery for introduction into interstate commerce of any . . . drug . . . that is adulterated or misbranded". "Any person" violating this provision is, by paragraph (a) of § 303 (21 U. S. C. § 333), made "guilty of a misdemeanor". Three counts went to the jury—two, for shipping misbranded drugs in interstate commerce, and a third, for so shipping an adulterated drug. The jury disagreed as to the corporation and found Dotterweich guilty on all three counts. We start with the finding of the Circuit Court of Appeals that the evidence was adequate to support the verdict of adulteration and misbranding. 131 F. 2d 500, 502.

Two other questions which the Circuit Court of Appeals decided against Dotterweich call only for summary disposition to clear the path for the main question before us. He invoked § 305 of the Act requiring the Administrator, before reporting a violation for prosecution by a United States attorney, to give the

suspect an "opportunity to present his views". We agree with the Circuit Court of Appeals that the giving of such an opportunity, which was not accorded to Dotterweich, is not a prerequisite to prosecution. This Court so held in *United States v. Morgan*, 222 U. S. 274, in construing the Food and Drugs Act of 1906, 34 Stat. 768, and the legislative history to which the court below called attention abundantly proves that Congress, in the changed phraseology of 1938, did not intend to introduce a change of substance. 83 Cong. Rec. 7792-94. Equally baseless is the claim of Dotterweich that, having failed to find the corporation guilty, the jury could not find him guilty. Whether the jury's verdict was the result of carelessness or compromise or a belief that the responsible individual should suffer the penalty instead of merely increasing, as it were, the cost of running the business of the corporation, is immaterial. Juries may indulge in precisely such motives or vagaries. *Dunn v. United States*, 284 U. S. 390.

And so we are brought to our real problem. The Circuit Court of Appeals, one judge dissenting, reversed the conviction on the ground that only the corporation was the "person" subject to prosecution unless, perchance, Buffalo Pharmaceutical was a counterfeit corporation serving as a screen for Dotterweich. On that issue, after rehearing, it remanded the cause for a new trial. We then brought the case here, on the Government's petition for certiorari, 318 U. S. 753, because this construction raised questions of importance in the enforcement of the Federal Food, Drug, and Cosmetic Act.

The court below drew its conclusion not from the provisions defining the offenses on which this prosecution was based (§§ 301(a) and 303(a)), but from the terms of § 303(e). That section affords immunity from prosecution if certain conditions are satisfied. The condition relevant to this case is a guaranty from the seller of the innocence of his product. So far as here relevant, the provision for an immunizing guaranty is as follows:

"No person shall be subject to the penalties of subsection (a) of this section . . . (2) for having violated section 301(a) or (d), if he establishes a guaranty or undertaking signed by, and containing the name and address of, the person residing in the United States from whom he received in good faith the article, to the effect, in case of an alleged violation of section 301(a), that such article is not adulterated or misbranded, within the meaning of this Act, designating this Act"

The Circuit Court of Appeals found it "difficult to believe that Congress expected anyone except the principal to get such a guaranty, or to make the guilt of an agent depend upon whether his employer had gotten one." 131 F. 2d 500, 503. And so it cut down the scope of the penalizing provisions of the Act to the restrictive view, as a matter of language and policy, it took of the relieving effect of a guaranty.

The guaranty clause cannot be read in isolation. The Food and Drugs Act of 1906 was an exertion by Congress of its power to keep impure and adulterated food and drugs out of the channels of commerce. By the Act of 1938, Congress extended the range of its control over illicit and noxious articles and stiffened the penalties for disobedience. The purposes of this legislation thus touch phases of the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection. Regard for these purposes should infuse construction of the legislation if it is to be treated as a working instrument of government and not merely as a collection of English words. See *Hipolite Egg Co. v. United States*, 220 U. S. 45, 57, and *McDermott v. Wisconsin*, 228 U. S. 115, 128. The prosecution to which Dotterweich was subjected is based on a now familiar type of legislation whereby penalties serve as effective means of regulation. Such legislation dispenses with the conventional requirement for criminal conduct—awareness of some wrongdoing. In the interest of the larger good it puts the burden of acting at hazard upon a person otherwise innocent but standing in responsible relation to a public danger. *United States v. Balint*, 258 U. S. 259. And so it is clear that shipments like those now in issue are "punished by the statute if the article is misbranded [or adulterated], and that the article may be misbranded [or adulterated] without any conscious fraud at all. It was natural enough to throw this risk on shippers with regard to the identity of their wares" *United States v. Johnson*, 221 U. S. 488, 497-98.

The statute makes "any person" who violates § 301(a) guilty of a "misdemeanor". It specifically defines "person" to include "corporation". § 201(e). But the only way in which a corporation can act is through the individuals who act on its behalf. *New York Central R. R. v. United States*, 212 U. S. 481. And the historic conception of a "misdemeanor" makes all those responsible for it equally guilty. *United States v. Mills*, 7 Pet. 138, 141, a doc-

trine given general application in § 332 of the Penal Code (18 U. S. C. § 550). If, then, Dotterweich is not subject to the Act, it must be solely on the ground that individuals are immune when the "person" who violates § 301(a) is a corporation, although from the point of view of action the individuals are the corporation. As a matter of legal development, it has taken time to establish criminal liability also for a corporation and not merely for its agents. See *New York Central R. R. v. United States, supra*. The history of federal food and drug legislation is a good illustration of the elaborate phrasing that was in earlier days deemed necessary to fasten criminal liability on corporations. Section 12 of the Food and Drugs Act of 1906 provided that, "the act, omission, or failure of any officer, agent, or other person acting for or employed by any corporation, company, society, or association, within the scope of his employment or office, shall in every case be also deemed to be the act, omission, or failure of such corporation, company, society, or association as well as that of the person." By 1938, legal understanding and practice had rendered such statement of the obvious superfluous. Deletion of words—in the interest of brevity and good draftsmanship¹—superfluous for holding a corporation criminally liable can hardly be found ground for relieving from such liability the individual agents of the corporation. To hold that the Act of 1938 freed all individuals, except when proprietors, from the culpability under which the earlier legislation had placed them is to defeat the very object of the new Act. Nothing is clearer than that the later legislation was designed to enlarge and stiffen the penal net and not to narrow and loosen it. This purpose was unequivocally avowed by the two committees which reported the bills to the Congress. The House Committee reported that the Act "seeks to set up effective provisions against abuses of consumer welfare growing out of inadequacies in the Food and Drugs Act of June 30, 1906." (H. Rep. No. 2139, 75th Cong., 3d Sess., p. 1.) And the Senate Committee explicitly pointed out that the new legislation "must not weaken the existing laws", but on the contrary "it must strengthen and extend that law's protection of the consumer." (S. Rep. No. 152, 75th Cong., 1st Sess., p. 1.) If the 1938 Act were construed as it

¹ "The bill has been made shorter and less verbose than previous bills. That has been done without deleting any effective provisions." S. Rep. No. 152, 75th Cong., 1st Sess., p. 2.

was below, the penalties of the law could be imposed only in the rare case where the corporation is merely an individual's *alter ego*. Corporations carrying on an illicit trade would be subject only to what the House Committee described as a "license fee for the conduct of an illegitimate business."² A corporate officer, who even with "intent to defraud or mislead" (§ 303b), introduced adulterated or misbranded drugs into interstate commerce could not be held culpable for conduct which was indubitably outlawed by the 1906 Act. See, e.g., *United States v. Mayfield*, 177 F. 765. This argument proves too much. It is not credible that Congress should by implication have exonerated what is probably a preponderant number of persons involved in acts of disobedience—for the number of non-corporate proprietors is relatively small. Congress, of course, could reverse the process and hold only the corporation and allow its agents to escape. In very exceptional circumstances it may have required this result. See *Sherman v. United States*, 282 U. S. 25. But the history of the present Act, its purposes, its terms, and extended practical construction lead away from such a result once "we free our minds from the notion that criminal statutes must be construed by some artificial and conventional rule". *United States v. Union Supply Co.*, 215 U. S. 50, 55.

The Act is concerned not with the proprietary relation to a misbranded or an adulterated drug but with its distribution. In the case of a corporation such distribution must be accomplished, and may be furthered, by persons standing in various relations to the incorporeal proprietor. If a guaranty immunizes shipments of course it immunizes all involved in the shipment. But simply because if there had been a guaranty it would have been received by the proprietor, whether corporate or individual, as a safeguard for the enterprise, the want of a guaranty does not cut down the scope of responsibility of all who are concerned with transactions forbidden by § 301. To be sure, that casts the risk that there is no guaranty upon all who according to settled doctrines of criminal law are responsible for the commission of a misdemeanor. To read the guaranty section, as did the court below, so as to restrict liability for penalties to the only person

²In describing the penalty provisions of § 303, the House Committee reported that the Bill "increases substantially the criminal penalties which some manufacturers have regarded as substantially a license fee for the conduct of an illegitimate business." H. Rep. No. 2139, 75th Cong., 3d Sess., p. 4.

who normally would receive a guaranty—the proprietor—disregards the admonition that “the meaning of a sentence is to be felt rather than to be proved”. *United States v. Johnson*, 221 U. S. 488, 496. It also reads an exception to an important provision safeguarding the public welfare with a liberality which more appropriately belongs to enforcement of the central purpose of the Act.

The Circuit Court of Appeals was evidently tempted to make such a devitalizing use of the guaranty provision through fear that an enforcement of § 301(a) as written might operate too harshly by sweeping within its condemnation any person however remotely entangled in the proscribed shipment. But that is not the way to read legislation. Literalism and evisceration are equally to be avoided. To speak with technical accuracy, under § 301 a corporation may commit an offense and all persons who aid and abet its commission are equally guilty. Whether an accused shares responsibility in the business process resulting in unlawful distribution depends on the evidence produced at the trial and its submission—assuming the evidence warrants it—to the jury under appropriate guidance. The offense is committed, unless the enterprise which they are serving enjoys the immunity of a guaranty, by all who do have such a responsible share in the furtherance of the transaction which the statute outlaws, namely, to put into the stream of interstate commerce adulterated or misbranded drugs. Hardship there doubtless may be under a statute which thus penalizes the transaction though consciousness of wrongdoing be totally wanting. Balancing relative hardships, Congress has preferred to place it upon those who have at least the opportunity of informing themselves of the existence of conditions imposed for the protection of consumers before sharing in illicit commerce, rather than to throw the hazard on the innocent public who are wholly helpless.

It would be too treacherous to define or even to indicate by way of illustration the class of employees which stands in such a responsible relation. To attempt a formula embracing the variety of conduct whereby persons may responsibly contribute in furthering a transaction forbidden by an Act of Congress, to wit, to send illicit goods across state lines, would be mischievous futility. In such matters the good sense of prosecutors, the wise guidance of trial judges, and the ultimate judgment of juries must

be trusted. Our system of criminal justice necessarily depends on "conscience and circumspection in prosecuting officers" - *Nash v. United States*, 229 U. S. 373, 378, even when the consequences are far more drastic than they are under the provision of law before us. See *United States v. Balint*, *supra* (involving a maximum sentence of five years). For present purpose it suffices to say that in what the defense characterized as "a very fair charge" the District Court properly left the question of the responsibility of Dotterweich for the shipment to the jury, and there was sufficient evidence to support its verdict.

Judgment reversed.

SUPREME COURT OF THE UNITED STATES.

No. 5.—OCTOBER TERM, 1943.

The United States of America, Petitioner,
vs.
Joseph H. Dotterweich.

On Writ of Certiorari to the
United States Circuit Court
of Appeals for the Second
Circuit.

[November 22, 1943.]

Mr. Justice MURPHY, dissenting.

Our prime concern in this case is whether the criminal sanctions of the Federal Food, Drug, and Cosmetic Act of 1938 plainly and unmistakably apply to the respondent in his capacity as a corporate officer. He is charged with violating § 301(a) of the Act, which prohibits the introduction or delivery for introduction into interstate commerce of any adulterated or misbranded drug. There is no evidence in this case of any personal guilt on the part of the respondent. There is no proof or claim that he ever knew of the introduction into commerce of the adulterated drugs in question, much less that he actively participated in their introduction. Guilt is imputed to the respondent solely on the basis of his authority and responsibility as president and general manager of the corporation.

It is a fundamental principle of Anglo-Saxon jurisprudence that guilt is personal and that it ought not lightly to be imputed to a citizen who, like the respondent, has no evil intention or consciousness of wrongdoing. It may be proper to charge him with responsibility to the corporation and the stockholders for negligence and mismanagement. But in the absence of clear statutory authorization it is inconsistent with established canons of criminal law to rest liability on an act in which the accused did not participate and of which he had no personal knowledge. Before we place the stigma of a criminal conviction upon any such citizen the legislative mandate must be clear and unambiguous. Accordingly that which Chief Justice Marshall has called "the tenderness of the law for the rights of individuals"¹

¹ United States v. Wiltberger, 5 Wheat. 76, 95.

entitles each person, regardless of economic or social status, to an unequivocal warning from the legislature as to whether he is within the class of persons subject to vicarious liability. Congress cannot be deemed to have intended to punish anyone who is not "plainly and unmistakably" within the confines of the statute. *United States v. Lacher*, 134 U. S. 624, 628; *United States v. Gradwell*, 243 U. S. 476, 485.

Moreover, the fact that individual liability of corporate officers may be consistent with the policy and purpose of a public health and welfare measure does not authorize this Court to impose such liability where Congress has not clearly intended or actually done so. Congress alone has the power to define a crime and to specify the offenders. *United States v. Wiltberger*, 5 Wheat. 76, 95. It is not our function to supply any deficiencies in these respects, no matter how grave the consequences. Statutory policy and purpose are not constitutional substitutes for the requirement that the legislature specify with reasonable certainty those individuals it desires to place under the interdict of the Act. *United States v. Harris*, 177 U. S. 305; *Sarlls v. United States*, 152 U. S. 570.

Looking at the language actually used in this statute, we find a complete absence of any reference to corporate officers. There is merely a provision in § 303(a) to the effect that "any person" inadvertently violating § 301(a) shall be guilty of a misdemeanor. Section 201(e) further defines "person" as including an "individual, partnership, corporation, and association."² The fact that a corporate officer is both a "person" and an "individual" is not indicative of an intent to place vicarious liability on the officer. Such words must be read in light of their statutory environment.³ Only if Congress has otherwise specified an intent

² The normal and necessary meaning of such a definition of "person" is to distinguish between individual enterprises and those enterprises that are incorporated or operated as a partnership or association, in order to subject them all to the Act. This phrase cannot be considered as an attempt to distinguish between individual officers of a corporation and the corporate entity. Lee, "Corporate Criminal Liability," 28 Col. L. Rev. 1, 181, 190.

³ Compare *United States v. Coöper Corp.*, 312 U. S. 600, 606, and *Davis v. Pringle*, 268 U. S. 315, 318, holding that the context and legislative history of the particular statutes there involved indicated that the words "any person" did not include the United States. But in *Georgia v. Evans*, 316 U. S. 159, and *Ohio v. Helvering*, 292 U. S. 360, these considerations led to the conclusion that "any person" did include a state. See also 40 Stat. 1143, which specifically includes officers within the meaning of "any person" as used in the Revenue Act of 1918.

to place corporate officers within the ambit of the Act can they be said to be embraced within the meaning of the words "person" or "individual" as here used.

Nor does the clear imposition of liability on corporations reveal the necessary intent to place criminal sanctions on their officers. A corporation is not the necessary and inevitable equivalent of its officers for all purposes.⁴ In many respects it is desirable to distinguish the latter from the corporate entity and to impose liability only on the corporation. In this respect it is significant that this Court has never held the imposition of liability on a corporation sufficient, without more, to extend liability to its officers who have no consciousness of wrongdoing.⁵ Indeed, in a closely analogous situation, we have held that the vicarious personal liability of receivers in actual charge and control of a corporation could not be predicated on the statutory liability of a "company," even when the policy and purpose of the enactment were consistent with personal liability. *United States v. Harris, supra.*⁶ It follows that express statutory provisions are

⁴ In *Park Bank v. Remsen*, 158 U. S. 337, 344, this Court said, "It is the corporation which is given the powers and privileges and made subject to the liabilities. Does this carry with it an imposition of liability upon the trustee or other officer of the corporation? The officer is not the corporation; his liability is personal, and not that of the corporation, nor can it be counted among the powers and privileges of the corporation."

⁵ For an analysis of the confusion on this matter in the state and lower federal courts, see Lee, "Corporate Criminal Liability," 28 Col. L. Rev. 1, 181.

⁶ In that case we had before us Rev. Stat. §§ 4386-4389, which penalized "any company, owner or custodian of such animals" who failed to comply with the statutory requirements as to livestock transportation. A railroad company violated the statute and the government sought to impose liability on the receivers who were in actual charge of the company. It was argued that the word "company" embraced the natural persons acting on behalf of the company and that to hold such officers and receivers liable was within the policy and purpose of so humane a statute. We rejected this contention in language peculiarly appropriate to this case (177 U. S. at 309):

"It must be admitted that, in order to hold the receivers, they must be regarded as included in the word 'company.' Only by a strained and artificial construction, based chiefly upon a consideration of the mischief which the legislature sought to remedy, can receivers be brought within the terms of the law. But can such a kind of construction be resorted to in enforcing a penal statute? Giving all proper force to the contention of counsel of the government, that there has been some relaxation on the part of the courts in applying the rule of strict construction to such statutes, it still remains that the intention of a penal statute must be found in the language actually used, interpreted according to its fair and obvious meaning. It is not permitted to courts, in this class of cases, to attribute inadvertence or oversight to the legislature when enumerating the classes of persons who are subjected to a penal enactment, nor to depart from the settled meaning of words or phrases in order to bring persons not named or distinctly described within the supposed purpose of the statute."

necessary to satisfy the requirement that officers as individuals be given clear and unmistakable warning as to their vicarious personal liability. This Act gives no such warning.

This fatal hiatus in the Act is further emphasized by the ability of Congress, demonstrated on many occasions, to apply statutes in no uncertain terms to corporate officers as distinct from corporations.⁷ The failure to mention officers specifically is thus some indication of a desire to exempt them from liability. In fact the history of federal food and drug legislation is itself illustrative of this capacity for specification and lends strong support to the conclusion that Congress did not intend to impose liability on corporate officers in this particular Act.

Section 2 of the Federal Food and Drugs Act of 1906, as introduced and passed in the Senate, contained a provision to the effect that any violation of the Act by a corporation should be deemed to be the act of the officer responsible therefor and that such officer might be punished as though it were his personal act.⁸ This clear imposition of criminal responsibility on corporate officers, however, was not carried over into the statute as finally enacted. In its place appeared merely the provision that "when construing and enforcing the provisions of this Act, the act, omission, or failure of any officer, agent, or other person

⁷ "Whenever a corporation shall violate any of the penal provisions of the antitrust laws, such violation shall be deemed to be also that of the individual directors, officers, or agents of such corporation who shall have authorized, ordered, or done any of the acts constituting in whole or in part such violation." 15 U. S. C. § 24.

"The courts of bankruptcy . . . are invested . . . with such jurisdiction at law and in equity as will enable them to . . . (4) arraign, try, and punish bankrupts, officers, and other persons, and the agents, officers, members of the board of directors or trustees, or other similar controlling bodies, of corporations for violations of ~~the provisions contained in this title.~~" 45 U. S. C. § 61.

"Any such common carrier, or any officer or agent thereof, requiring or permitting any employee to go, be, or remain on duty in violation of the next preceding section of this chapter shall be liable to a penalty . . . 45 U. S. C. § 63.

"A mortgagor who, with intent to defraud, violates any provision of subsection F, section 924, and if the mortgagor is a corporation or association, the president or other principal executive officer of the corporation or association, shall upon conviction thereof be held guilty of a misdemeanor . . . 46 U. S. C. § 941(b).

8 S. 88, 59th Cong., 1st Sess. Senator Heyburn, one of the sponsors of S. 88, stated that this was "a new feature in bills of this kind. It was intended to obviate the possibility of escape by officers of a corporation under a plea, which has been more than once made, that they did not know that this was being done on the credit of or on the responsibility of the corporation." 40 Cong. Rec. 894.

acting for or employed by any corporation . . . within the scope of his employment or office, shall in every case be also deemed to be the act, omission, or failure of such corporation . . . as well as that of the person."⁹ This provision had the effect only of making corporations responsible for the illegal acts of their officers and proved unnecessary in view of the clarity of the law to that effect. *New York Central & H. R. R. Co. v. United States*, 212 U. S. 481.

The framers of the 1938 Act were aware that the 1906 Act was deficient in that it failed "to place responsibility properly upon corporate officers."¹⁰ In order "to provide the additional scope necessary to prevent the use of the corporate form as a shield to individual wrongdoers,"¹¹ these framers inserted a clear provision that "whenever a corporation or association violates any of the provisions of this Act, such violation shall also be deemed to be a violation of the individual directors, officers, or agents of such corporation or association who authorized, ordered, or did any of the acts constituting, in whole or in part, such violation."¹² This paragraph, however, was deleted from the final version of the Act.

We cannot presume that this omission was inadvertent on the part of Congress. *United States v. Harris*, *supra* at 309. Even if it were, courts have no power to remedy so serious a defect, no matter how probable it otherwise may appear that Congress in-

⁹ 34 Stat. 772, 21 U. S. C. § 4.

¹⁰ Senate Report No. 493, 73d Cong., 2d Sess., p. 21.

¹¹ *Ibid.*, p. 22. This report also stated that "it is not, however, the purpose of this paragraph to subject to liability those directors, officers, and employees, who merely authorize their subordinates to perform lawful duties and such subordinates, on their own initiative, perform those duties in a manner which violates the provisions of the law. However, if a director or officer personally orders his subordinate to do an act in violation of the law, there is no reason why he should be shielded from personal responsibility merely because the act was done by another and on behalf of a corporation."

¹² This provision appears in several of the early versions of the Act introduced in Congress. S. 1944, 73d Cong., 1st Sess., § 18(b); S. 2000, 73d Cong., 2d Sess., § 18(b); S. 2800, 73d Cong., 2d Sess., § 18(b); S. 5, 74th Cong., 1st Sess. § 709(b); S. 5, 74th Cong., 2d Sess., § 707(b), as reported to the House, which substituted the word "personally" for the word "authorized" in the last clause of the paragraph quoted above. A variation of this provision appeared in S. 5, 75th Cong., 1st Sess. § 2(f), and made a marked distinction between the use of the word "person" and the words "director, officer, employee, or agent acting for or employed by any person." All of these bills also contained the present definition of "person" as including "individual, partnership, corporation, and association."

tended to include officers; "probability is not a guide which a court, in construing a penal statute, can safely take." *United States v. Wiltberger, supra* at 105. But the framers of the 1938 Act had an intelligent comprehension of the inadequacies of the 1906 Act and of the unsettled state of the law. They recognized the necessity of inserting clear and unmistakable language in order to impose liability on corporate officers. It is thus unreasonable to assume that the omission of such language was due to a belief that the Act as it now stands was sufficient to impose liability on corporate officers. Such deliberate deletion is consistent only with an intent to allow such officers to remain free from criminal liability. Thus to apply the sanctions of this Act to the respondent would be contrary to the intent of Congress as expressed in the statutory language and in the legislative history.

The dangers inherent in any attempt to create liability without express Congressional intention or authorization are illustrated by this case. Without any legislative guides, we are confronted with the problem of determining precisely which officers, employees and agents of a corporation are to be subject to this Act by our fiat. To erect standards of responsibility is a difficult legislative task and the opinion of this Court admits that it is "too treacherous" and a "mischievous futility" for us to engage in such pursuits. But the only alternative is a blind resort to "the good sense of prosecutors, the wise guidance of trial judges, and the ultimate judgment of juries." Yet that situation is precisely what our constitutional system sought to avoid. Reliance on the legislature to define crimes and criminals distinguishes our form of jurisprudence from certain less desirable ones. The legislative power to restrain the liberty and to imperil the good reputation of citizens must not rest upon the variable attitudes and opinions of those charged with the duties of interpreting and enforcing the mandates of the law. I therefore cannot approve the decision of the Court in this case.

Mr. Justice ROBERTS, Mr. Justice REED and Mr. Justice RUTLEDGE join in this dissent.